SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MON.FDG (^{18}F) vial containing solution for I.V. injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:
1 ml of the solution contains 250 MBq Fluorodeoxyglucose (^{18}F) at the date and hour of calibration.

The activity per vial ranges from 250 MBq -18.5 GBq at the date and time of calibration.
Fluorine (^{18}F) decays to stable oxygen (^{18}O) with a half-life of 110 minutes by emitting a positronic radiation of maximum energy of 634 keV, followed by photonic annihilation radiations of 511 keV.

Excipients:
Ethanol 16.6 mg/mL

See section 6.1 for a list of excipients

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
This medicinal product is for diagnostic use only.

Fludeoxyglucose (^{18}F) is indicated for use with positron emission tomography (PET) in adults and paediatric population.

Oncology
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 (see also section 4.4):

Diagnosis
- Characterisation of solitary pulmonary nodule

- Detection of cancer of unknown origin, revealed for example by cervical adenopathy, liver or bones metastases
- Characterisation of a pancreatic mass

Staging
- Head and neck cancers including assistance in guiding biopsy
- Primary lung cancer
- Locally advanced breast cancer
- Oesophageal cancer
- Carcinoma of the pancreas
- Colorectal cancer particularly in restaging recurrences
- Malignant lymphoma
- Malignant melanoma, Breslow >1.5 mm or lymph node metastasis at first diagnosis

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 radioactive iodine whole body scintigraphy
- Primary lung cancer
- Breast cancer
- Carcinoma of the pancreas
- Colorectal cancer
- Ovarian 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

Infectious or inflammatory diseases
In infectious or inflammatory diseases, the diagnostic target is tissue or structures with an abnormal content of activated white blood cells.

In infectious or inflammatory diseases, the following indications are sufficiently documented:

Localisation of abnormal foci guiding the aetiologic diagnosis in case of fever of unknown origin

Diagnosis of infection in case of:
- Suspected chronic infection of bone and/or adjacent structures: osteomyelitis, spondilitis, diskitis or osteitis including when metallic implants are present
- Diabetic patient with a foot suspicious of Charcot's neuroarthropathy, osteomyelitis and/or soft tissue infection
- Painful hip prosthesis
- Vascular prosthesis
- Fever in an AIDS patient
- Detection of septic metastatic foci in case of bacteraemia or endocarditis (see also section 4.4).

Detection of the extension of inflammation in case of:
- Sarcoidosis
- Inflammatory bowel disease
- Vasculitis involving the great vessels

Therapy follow-up:
Unresectable alveolar echinococcosis, in search for active localisations of the parasite during medical treatment and after treatment discontinuation.

4.2 Posology and method of administration

Posology**:**

Adults and elderly population
The recommended MON.FDG (^{18}F) activity for an adult (70 kg) is 100-400 MBq (2.7-10,8 mCi) by intravenous administration (this activity has to be adapted according to the body weight of the patient, the type of camera used and acquisition mode).

Renal and hepatic impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Extensive dose-range and adjustment studies with this medicinal product in normal and special populations have not been performed.

The pharmacokinetics of fludeoxyglucose (^{18}F) in renally impaired patients has not been characterised.

Paediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) paediatric dosage card; the activity administered to children and to adolescents may be calculated by multiplying a baseline activity (for calculation purposes) by the weight-dependent multiples given in the table below.

$$A[MBq]_{Administered} = \text{Baseline Activity} \times \text{Multiple}$$

The baseline activity for 2D imaging is 25.9 MBq and for 3D imaging 14.0 MBq (recommended in children).

Weight [kg]	Multiple	Weight [kg]	Multiple	Weight [kg]	Multiple
3	1	22	5.29	42	9.14
4	1.14	24	5.71	44	9.57
6	1.71	26	6.14	46	10.00
8	2.14	28	6.43	48	10.29
10	2.71	30	6.86	50	10.71
12	3.14	32	7.29	52-54	11.29
14	3.57	34	7.72	56-58	12.00
16	4.00	36	8.00	60-62	12.71
18	4.43	38	8.43	64-66	13.43
20	4.86	40	8.86	68	14.00

Method of administration

For intravenous use.

For single or multidose use.

The activity of fludeoxyglucose (^{18}F) has to be measured with dose calibrator immediately prior to injection.

The injection of fludeoxyglucose (^{18}F) must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts.

For instructions on dilution of the medicinal product before administration, see section 12.
Instructions for preparation of radiopharmeutıcals

For patient preparation, see section 4.4.Special warnings and precautions for use

Image acquisition
The emission scans are usually started 45 to 60 minutes after the injection of fludeoxyglucose (^{18}F). Provided a sufficient activity remains for adequate counting statistics, fludeoxyglucose (^{18}F)-PET can also be performed up to two or three hours after administration, thus reducing background activity.

If required, repeated fludeoxyglucose (^{18}F) PET examinations can be reiterated within a short period of time.

4.3 Contraindications
It is contraindicated;
- For patients with sensitivity to active substance,
- For diabetic patients whose glucose level may not be controlled,
- During pregnancy,
- For lactation.

4.4 Special warnings and precautions for use
RADIOPHARMACEUTICALS SHOULD BE ADMINISTERED ONLY BY NUCLEAR MEDICINE PHYSICIANS IN NUCLEAR MEDICINE CENTERS.

The acceptance, storage and transfer of radiopharmaceuticals should be in accordance with the special regulations.

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

Individual benefit/risk justification
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Renal and hepatic impairment
Due to the major renal excretion of fludeoxyglucose (^{18}F), in patients with reduced kidney function, careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible. Activity should be adjusted if necessary.
Paediatric population

For information on the use in paediatric population, see sections 4.2 or 5.1.
Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).

Patient preparation
MON.FDG (^{18}F) should be given to sufficiently hydrated patients fasting for a minimum of 4 hours, in order to obtain a maximum target activity, since glucose uptake in the cells is limited ("saturation kinetics"). The amount of liquid should not be limited (beverages containing glucose must be avoided).

In order to obtain images of best quality and to reduce the radiation exposure of the bladder, patients should be encouraged to drink sufficient amounts and to empty their bladder prior to and after the PET examination.

- *Oncology and neurology and infectious diseases*
In order to avoid hyperfixation of the tracer in muscle, it is advisable for patients to avoid all strenuous physical activity prior to the examination and to remain at rest between the injection and examination and during acquisition of images (patients should be comfortably lying down without reading or speaking).

The cerebral glucose metabolism depends on the brain activity. Thus, neurological examinations should be performed after a relaxation period in a darkened room and with low background noise.

A blood glucose test should be performed prior to administration since hyperglycaemia may result in a reduced sensitivity of MON.FDG (^{18}F), especially when glycaemia is greater than 8 mmol/L. Similarly, PET with fludeoxyglucose (^{18}F) should be avoided in subjects presenting uncontrolled diabetes.

- *Cardiology*
Since glucose uptake in the myocardium is insulin-dependent, for a myocardial examination a glucose loading of 50 g approximately 1 hour prior to the administration of MON.FDG (^{18}F) is recommended. Alternatively, especially for patients with diabetes mellitus, the blood sugar level can be adjusted by a combined infusion of insulin and glucose (insulin-glucose-clamp) if needed.

Interpretation of the PET with fludeoxyglucose (^{18}F) images
In the exploration of inflammatory bowel diseases, diagnostic performance of fludeoxyglucose (^{18}F) has not been directly compared with that of scintigraphy using labelled white blood cells which may be indicated prior to fludeoxyglucose (^{18}F) PET or after fludeoxyglucose (^{18}F) PET when inconclusive.

Infectious and/or inflammatory diseases as well as regenerative processes after surgery can result in a significant uptake of fludeoxyglucose (^{18}F) and therefore lead to false

positive results, when search for infectious or inflammatory lesions is not the aim of the fludeoxyglucose (^{18}F) PET. In cases where fludeoxyglucose (^{18}F) accumulation can be caused by either cancer, infection or inflammation, additional diagnostic techniques for the determination of the causative pathologic alteration may be required to supplement the information obtained by PET with fludeoxyglucose (^{18}F). In some settings e.g. staging of myeloma, both malignant and infectious foci are searched for and may be distinguished with a good accuracy on topographic criteria e.g. uptake at extramedullary sites and/or bone and joint lesions would be atypical for multiple myeloma lesions and identified cases associated with infection. There are currently no other criteria to distinguish infection and inflammation by means of fludeoxyglucose (^{18}F) imaging.

Because of the high physiologic uptake of fludeoxyglucose (^{18}F) within brain, heart and kidneys, PET/CT with fludeoxyglucose (^{18}F) has not been evaluated for the detection of septic metastatic foci in these organs when the patient has been referred due to bacteraemia or endocarditis.

False positive or false negative PET with fludeoxyglucose (^{18}F) results cannot be excluded after radiotherapy within the first 2-4 months. If the clinical indication is demanding an earlier diagnosis by PET with fludeoxyglucose (^{18}F), the reason for earlier PET with fludeoxyglucose (^{18}F) examination must be reasonably documented.

A delay of at least 4-6 weeks after the last administration of chemotherapy is optimal, in particular to avoid false negative results. If the clinical indication is demanding an earlier diagnosis by PET with fludeoxyglucose (^{18}F), the reason for earlier PET with fludeoxyglucose (^{18}F) examination must be reasonably documented. In case of chemotherapy regimen with cycles shorter than 4 weeks, the PET with fludeoxyglucose (^{18}F) examination should be done just before re-starting a new cycle.

In low-grade lymphoma, lower oesophagus cancer and suspicion of recurrent ovarian cancer, only positive predictive values have to be considered because of a limited sensitivity of PET with fludeoxyglucose (^{18}F).

Fludeoxyglucose (^{18}F) is not effective in detecting brain metastases.

Since sensitivity will decrease depending on the dedicated PET when a coincidence PET screening system is used, lesions smaller than 1cm are detected less.

The accuracy of fludeoxyglucose (^{18}F) PET imaging is better using PET/CT than PET cameras alone.

When a hybrid PET-CT scanner is used with or without administration CT contrast media, some artefacts may occur on the attenuation-corrected PET images.
It is recommended that (^{18}F) FDG-PET images be evaluated in correlation where necessary by means of tomographic anatomic screening methods. The combination of

functional fluorodeoxyglucose (^{18}F)-PET screening with systems that allow morphological screening (such as PET-CT) will increase the sensitivity and uniqueness. Therefore, in respect of pancreas, head-neck tumors, lymph, lung cancers and recurring colorectal cancers, the correlation with anatomic screening methods is recommended.

MON.FDG (^{18}F) should be stored and operated in lead or tungsten shields in a way to ensure sufficient protection, in order to protect the patient and hospital personnel as much as possible. Especially when pulling away medicine from vial and while performing injection, it is recommended that the person be protected by an appropriate shielding against the radiation given off by positron and annihilation photons.

After the procedure
Close contact with infants and pregnant women should be restricted during the initial 12 hours following the injection.

Specific warnings
This medicinal product includes a small amount of ethanol (alcohol) [i.e. lower than 100 mg for every administration dose (maximum 3 mL)].

Precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction
All medicinal products that modify blood glucose levels can affect the sensitivity of the examination (e.g. corticosteroids, valproate, carbamazepine, phenytoin, phenobarbital and catecholamines).

Under administration of colony-stimulating factors (CSFs), there is an increased uptake of fludeoxyglucose (^{18}F) in the bone marrow and the spleen for several days. This must be taken into account for the interpretation of PET imaging. Separating CSF therapy from PET imaging by an interval of at least 5 days may diminish this interference.

The administration of glucose and insulin influences the influx of fludeoxyglucose (^{18}F) into the cells. In the case of high blood glucose levels as well as low plasma insulin levels, the influx of fludeoxyglucose (^{18}F) into organs and tumours is reduced.

No formal studies on the interaction between fludeoxyglucose (^{18}F) and any contrast for computed tomography have been performed.

Additional information on special population
Not applicable.

Paediatric population
Not applicable.
4.6 Pregnancy and lactation

General recommendation
Pregnancy category: X

Women of childbearing potential / Contraception
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

The MON.FDG (^{18}F) application which has 400 MBq activity will result in 8.4 mGY absorbed radiation dose in uterus. At this dose interval no lethal effects, start of malformation, delay in development and functional disorders are not expected, yet cancer induction and genetic defects may increase.

Pregnancy
When radiation is applied during the pregnancy period, it leads to serious birth defects.
MON.FDG (^{18}F) is contraindicated during pregnancy period.

Lactation
Fluorodeoxyglucose (^{18}F) is discarded through breast milk.
MON.FDG (^{18}F) is contraindicated during lactation period.

Fertility
Its effect on the fertility is unknown since no chronic toxicity, mutagenic potential and fertility toxicity and carcinogenic potential studies are conducted.
No studies on fertility have been performed.

4.7 Effects on ability to drive and use machines
There is no data as to that vehicle must not be driven and any machine must not be operated.

4.8 Undesirable effects
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 7.6 mSv when the maximal recommended activity of 400 MBq is administered these adverse reactions are expected to occur with a low probability.

<u>Reporting of suspected adverse reactions</u>
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

No overdose application is reported for MON.FDG (^{18}F).

In the event of administration of a radiation overdose with fludeoxyglucose (^{18}F) the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

5. PHARMACOLOGICAL PROPERTIES

MON.FDG (^{18}F) is an analogue of glucose which is labelled with radioisotope and distrubuted to all organs of the body after intravenous application. Screening may be received 45-60 minutes after the application.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceutical, other diagnostic radiopharmaceuticals for tumour detection

ATC Code: V09IX04

At the chemical concentrations used for diagnostic examinations, fludeoxyglucose (^{18}F) does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties

Distribution

Fludeoxyglucose (^{18}F) is a glucose analogue which is accumulated in all cells using glucose as primary energy source. Fludeoxyglucose (^{18}F) is accumulated in tumours with a high glucose turnover.

Following intravenous injection, the pharmacokinetic profile of fludeoxyglucose (^{18}F) in the vascular compartment is biexponential. It has a distribution time of 1 minute and an elimination time of approximately 12 minutes.

In healthy subjects, fludeoxyglucose (^{18}F) is widely distributed throughout the body, particularly in the brain and heart, and to a lesser degree in the lungs and liver.

Organ uptake

The cellular uptake of fludeoxyglucose (^{18}F) is performed by tissue-specific carrier systems which are partly insulin-dependent and, thus, can be influenced by eating, nutritional condition and the existence of a diabetes mellitus. In patients with a diabetes mellitus a reduced uptake of fludeoxyglucose (^{18}F) into the cells occurs due to a changed tissue distribution and glucose metabolism.

Fludeoxyglucose (^{18}F) is transported via the cell membrane in similar fashion to glucose, but only undergoes the first step of glycolysis resulting in formation of fludeoxyglucose (^{18}F)-6-phosphate which remains trapped within the tumour cells and is not further metabolised. Since the following dephosphorylation by intracellular phosphatases is slow, fludeoxyglucose (^{18}F)-6-phosphate is retained in the tissue over several hours (trapping-mechanism).

Fludeoxyglucose (^{18}F) passes the blood-brain barrier. Approximately 7 % of the injected dose are accumulated in the brain within 80-100 minutes after injection. Epileptogenic foci exhibit a reduced glucose metabolism in the seizure free phases.

Approximately 3 % of the injected activity is taken-up by the myocardium within 40 minutes. The distribution of fludeoxyglucose (^{18}F) in normal heart is mainly homogenous, however, regional differences of up to 15 % are described for the interventricular septum. During and after a reversible myocardial ischemia, an increased glucose uptake occurs into the myocardial cell.

0.3 % and 0.9 - 2.4 % of the injected activity are accumulated in pancreas and lung.

Fludeoxyglucose (^{18}F) is also bound to a lesser extent to ocular muscle, pharynx and intestine. Binding to muscle may be seen following recent exertion and in the event of muscular effort during the examination.

Elimination:
Elimination of fludeoxyglucose (^{18}F) is chiefly renal, with 20 % of activity being excreted in urine in the 2 hours following injection.

Binding to renal parenchyma is weak, but because of renal elimination of fludeoxyglucose (^{18}F), the entire urinary system, particularly the bladder, exhibits marked activity.

5.3 Preclinical safety data
Toxicological studies with mice and rats have demonstrated that with a single intravenous injection of 0.0002 mg/kg no deaths were observed. Toxicity with repeated administration was not performed because MON.FDG (^{18}F) is administered in a single dose. This medicinal product is not intended for regular or continuous administration.

Mutagenicity studies and long-term carcinogenicity studies have not been carried out.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for injection

Ethanol

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

It is 14 hours from manufacturing date and hour. Utilization permit of product is provided based to calibration hour. **It shouldn't be administered to the patient before calibration hour.**

6.4 Special precautions for storage

It should be stored in lead protection container in room temperature under 30 °C.

Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

6.5 Nature and content of container

10 ml colorless Type I borosilicate glass vial with bromobutil stopper and aluminum flip-off cap in lead shielded container. One vial contains maximum 10 ml solution and the activity in each vial varies between 250 MBq- 18,5 GBq at calibration date and time.

Single or multidose vial.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

General warning

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must be taken.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

222/53

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization: 21/12/2009

Date of last renewal: 25.05.2015

10. DATE OF REVISION OF THE TEXT

06.2025

11. DOSIMETRY

The data listed below are from ICRP 106 publication.

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adults**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.012	0.016	0.024	0.039	0.071
Bladder	0.13	0.16	0.25	0.34	0.47
Bone surfaces	0.011	0.016	0.022	0.034	0.064
Brain	0.038	0.039	0.041	0.046	0.063
Breasts	0.0088	0.011	0.018	0.029	0.056
Gallbladder	0.013	0.016	0.024	0.037	0.070
Gastrointestinal tract					
Stomach	0.011	0.014	0.022	0.035	0.067
Small intestine	0.012	0.016	0.025	0.040	0.073
Colon	0.013	0.016	0.025	0.039	0.070
(Upper large intestine	0.012	0.015	0.024	0.038	0.070)
(Lower large intestine	0.014	0.017	0.027	0.041	0.070)
Heart	0.067	0.087	0.13	0.21	0.38
Kidneys	0.017	0.021	0.029	0.045	0.078
Liver	0.021	0.028	0.042	0.063	0.12
Lungs	0.020	0.029	0.041	0.062	0.12
Muscles	0.010	0.013	0.020	0.033	0.062
Oesophagus	0.012	0.015	0.022	0.035	0.066
Ovaries	0.014	0.018	0.027	0.043	0.076
Pancreas	0.013	0.016	0.026	0.040	0.076
Red marrow	0.011	0.014	0.021	0.032	0.059
Skin	0.0078	0.0096	0.015	0.026	0.050
Spleen	0.011	0.014	0.021	0.035	0.066
Testes	0.011	0.014	0.024	0.037	0.066
Thymus	0.012	0.015	0.022	0.035	0.066
Thyroid	0.010	0.013	0.021	0.034	0.065
Uterus	0.018	0.022	0.036	0.054	0.090
Remaining organs	0.012	0.015	0.024	0.038	0.064
Effective dose (mSv/MBq)	**0.019**	**0.024**	**0.037**	**0.056**	**0.095**

The effective dose resulting from the administration of a maximal recommended activity of 400 MBq of fludeoxyglucose (^{18}F) for an adult weighing 70 kg is about 7.6 mSv.

For an administered activity of 400 MBq the typical radiation doses delivered to the critical organs, bladder, heart and brain are 52 mGy, 27 mGy and 15 mGy, respectively.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMEUTICALS

MON.FDG (^{18}F) is manufactured as ready to administer to patient. It is in 10 ml colorless Type I glass vial in lead shielded container.

While preparing patient dose, it should be worked at the back of lead shielding and should be conformed to aseptic conditions.

Before beginning to work, the vial should be checked visually.
Whether the solution contains particles and its transparency should be checked visually.

The solutions that are not transparent should not be used.

The patient dose should be taken through shielded injector that will provide radiation safety. Before procedure, vial plastic stopper should be cleaned with disinfectant.
Activity level should be determined through performing measurement at a dose calibrator.

Utilization permit of product is provided based to calibration hour. **It shouldn't be administered to the patient before calibration hour.**