PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

{(Invented) name strength pharmaceutical form}
FLUDEOXYGLUCOSE (^{18}F)

[Trade name = product specific.]

Read all of this leaflet carefully before you will be administered this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or the specialist physician in Nuclear Medicine who will supervise the procedure.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your referring doctor or the specialist physician in Nuclear Medicine who has supervised the procedure.

In this leaflet:

1. WHAT {(INVENTED) NAME} IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance contained in {(INVENTED) NAME} is designed for the capture of radiographical images of some parts of your body.

Once a small amount of {(INVENTED) NAME} has been injected, medical images that are obtained with a special camera will enable the physician to capture images and to see where your illness is or how it is progressing.

2. BEFORE {(INVENTED) NAME} IS ADMINISTERED

{(INVENTED) NAME} **must never be used**

- if you are allergic (hypersensitive) to fludeoxyglucose (^{18}F) or any of the other ingredients of {(INVENTED) NAME}

Take special care with {(INVENTED) NAME}

- if you are a diabetic and your diabetes is currently not equilibrated
- if you have an infection or an inflammatory disease

- if you are affected by renal disorders

Inform the specialist in Nuclear Medicine in the following cases;
- If you are pregnant or believe you may be pregnant
- if you are breast-feeding
- if you are under 18 years old

Using other medicines

Please tell your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure if you are taking or have recently taken any other medicines, (including medicines obtained without a prescription), since they may interfere with your physician's interpretation of the images:
- any medicine that may induce a modification of the blood sugar rate (glycemia), such as medicines having an effect on inflammation (corticosteroids), medicines against convulsions (valproate, carbamazepine, phenytoin, phenobarbital), medicines affecting the nervous system (adrenalin, noradrenalin, dopamin…),
- glucose,
- insulin,
- factors increasing the production of blood cells.

Using {(INVENTED) NAME} **with food and drink**

This medicine can only be injected in patients who have been fasting for at least 4 hours.
Blood sugar should be measured before administering the medicine; indeed a high blood glucose concentration (hyperglycemia) can make the physician's interpretation more difficult.

Pregnancy and breast-feeding

You must inform the specialist physician in Nuclear Medicine before the injection of {(INVENTED) NAME} if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.
When in doubt, it is important to consult your physician or the specialist physician in Nuclear Medicine who will supervise the procedure.

If you are pregnant
Your physician will only consider this examination during your pregnancy in case of absolute necessity.

If you are breast-feeding
You must stop breast-feeding for 12 hours after the injection and the maternal milk pumped must be discarded.
Resuming breast-feeding should be in agreement with the specialist in Nuclear Medicine who will supervise the procedure.

Please ask your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure before taking any medicines.

Before {(INVENTED) NAME} **administration you should:**
- avoid all important physical activity
- drink water abundantly during the 4 hours preceding the test
- be fasting for at least 4 hours

After administration of {(INVENTED) NAME} **has been performed, you should:**
- avoid any close contact with young children for the 12 hours following the injection

- urinate frequently in order to eliminate the product from your body

There are strict laws on the use, handling and disposal of radiopharmaceutical products. {(INVENTED) NAME} will only be used in a hospital. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

Driving and using machines

It is considered unlikely that {(INVENTED) NAME} will affect your ability to drive or to operate machinery.

Important information about some of the ingredients of {(INVENTED) NAME}

According to the time of conditioning injection for the patient, the content of sodium may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patient on low sodium diet.

3. HOW WILL {(INVENTED) NAME} BE USED?

The specialist physician in Nuclear Medecine supervising the procedure will decide on the quantity of {(INVENTED) NAME} to be used in your case. It will be the smallest quantity necessary to get the desired information.
The quantity to be administered usually recommended for an adult ranges from 100 to 400 MBq (depending on the patient's body mass, the type of camera used for imaging and the acquisition mode). Megabecquerel (MBq) is a metric measurement unit of radioactivity.

Use in children
In case of use in children, the quantity to be administered will be adapted to the child's body mass.

Administration of {(INVENTED) NAME} **and conduct of the procedure**

{(INVENTED) NAME} is administered intravenously.
One injection is sufficient to conduct the test that your physician needs.
After injection, you will be offered a drink and asked to urinate immediately preceding the test.

During the test, you will need **to be completely at rest, lying down comfortably, without reading nor talking.**

Duration of the procedure:

Your physician will inform you about the usual duration of the procedure.
Generally speaking,{(INVENTED) NAME} is administered as a single injection in a vein, 45-60 minutes before the imaging acquisition takes place. The imaging acquisition, thanks to the camera, lasts itself 30 to 60 minutes.

If you have been administered more {(INVENTED) NAME} **than you should**
An overdose is almost impossible because you will only receive a single dose of {(INVENTED) NAME} precisely controlled by the specialist physician supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the specialist physician in charge of the procedure may recommend that you drink abundantly in order to facilitate the elimination of {(INVENTED) NAME} from your body (indeed the principle way of elimination of this medicine is renal, in the urine).

Should you have any further question on the use of {(INVENTED) NAME}, please ask your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

4. POSSIBLE SIDE EFFECTS

Like all medicines, {(INVENTED) NAME} can cause side effects, although not everybody gets them. This administered radiopharmaceutical will deliver low amount of ionising radiation with very low risk of cancer and hereditary abnormalities.

Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

If you notice any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

5. FURTHER INFORMATION

What {(INVENTED) NAME} **contains**

- The active substance is fludeoxyglucose (^{18}F). 1 ml solution for injection contains <XXX> MBq fludeoxyglucose (^{18}F) at the date and time of calibration.
- The other ingredients are: {Product specific}

What {(INVENTED) NAME} **looks like and contents of the pack**

The activity per vial ranges from <XXX> MBq to <XXX> MBq at the date and time of calibration.

Marketing Authorisation Holder and Manufacturer

<This medicinal product is authorised in the Member States of the EEA under the following names:>

This leaflet was last approved in {MM/YYYY}.

<The following information is intended for medical or healthcare professionals only:>
The complete SmPC of {(INVENTED) NAME} is provided <as a separate document> <as a tear-off section at the end of the printed leaflet> in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC (SmPC should be included in the box)