PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
EFDEGE 1.0 GBq/mL, solution for injection
Fludeoxyglucose (^{18}F)

Read all of this leaflet carefully before you will be administered this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If any of the side effects, talk to your nuclear medicine. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What EFDEGE is and what is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance contained in **EFDEGE** is fludeoxyglucose (^{18}F) and is designed for the capture of diagnostic images of some parts of your body.
Once a small amount of EFDEGE has been injected medical images that are obtained with a special camera will enable the doctor to capture images and to see where your illness is or how it is progressing.

2. What you need to know before EFDEGE is used

EFDEGE must not be used

- if you are allergic to fludeoxyglucose (^{18}F) or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your nuclear medicine doctor before being administered EFDEGE:

- 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 kidney problems

Inform your nuclear medicine doctor in the following cases:

- if you are pregnant or believe you may be pregnant
- if you are breast-feeding

Before administration of EFDEGE you should:

- drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study
- avoid all important physical activity
- be fasting for at least 4 hours

Children and adolescents

Please talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and EFDEGE

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with your doctor'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,
- medicines used to increase the production of blood cells.

EFDEGE with food and drink

You should be fasting at least 4 hours before the administration of the product. You should drink plenty of water and avoid taking liquids containing sugar.

You nuclear medicine doctor will measure your blood sugar before administering the product, indeed a high blood glucose concentration (hyperglycaemia) can make the nuclear medicine doctor's interpretation more difficult.

Pregnancy and breast-feeding

You must inform the nuclear medicine doctor before the administration of EFDEGE 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 nuclear medicine doctor who will supervise the procedure.

If you are pregnant
The nuclear doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks

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 nuclear medicine who will supervise the procedure.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you will be administered this product.

Driving and using machines

It is considered unlikely that EFDEGE will affect your ability to drive or to use machines.

EFDEGE contains sodium

This product may contain more than 1 mmol of sodium (23 mg). You should take this into account if you are on a low sodium diet.

3. How EFDEGE will be used ?

There are strict laws on the use, handling and disposal of radiopharmaceutical products. EFDEGE will only be used in special controlled areas. 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.

The nuclear medicine doctor supervising the procedure will decide on the quantity of EFDEGE 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 the unit used to express radioactivity.

Use in children and adolescents

In case of use in children and adolescents , the quantity to be administered will be adapted to the child's weight.

Administration of EFDEGE and conduct of the procedure

EFDEGE is administered intravenously.
One injection is sufficient to conduct the test that your doctor needs.
After injection you will need to be completely at rest, without reading or talking. Also, you will be offered a drink and asked to urinate immediately preceding the procedure.

While the pictures are being taken, you will need **to be completely at rest**.

You should not move or talk.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

EFDEGE is administered as a single injection in a vein, 45-60 minutes before the imaging acquisition takes place. The imaging acquisition with the camera lasts 30 to 60 minutes.

After administration of EFDEGE, you should:

- avoid any close contact with young children and pregnant women for the 12 hours following the injection,
- urinate frequently in order to eliminate the product from your body.

If you have been administered more EFDEGE than you should

An overdose is almost impossible because you will only receive a single dose of EFDEGE precisely controlled by nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may recommend tha you drink abundantly in order to facilitate the elimination of EFDEGE from your body (indeed the principle way of elimination of this product is renal, in the urine).

If you have any further question on the use of EFDEGE, please ask your nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, EFDEGE can cause side effects, although not everybody gets them.
This radiopharmaceutical product will deliver low amount of ionising radiation with least 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.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How EFDEGE is stored

You will not have to store this product. This product is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.
The following information is intended for the specialist only.

This product must not be used after the expiry date which is stated on the label after {DD MM YYYY at hh:mm}

6. Content of the pack and other information

What EFDEGE contains

- The active substance is fludeoxyglucose (^{18}F). 1 mL solution for injection contains 1 GBq of fludeoxyglucose (^{18}F) at date and time of calibration.
- The other ingredients are: Sodium chloride and water for injection,

What EFDEGE looks like and contents of the pack

The activity per vial ranges from 0.2 GBq to 20.0 GBq at the date and time of calibration.

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

France	EFDEGE, solution injectable
Austria	EFDEGE – Injektionslösung
Belgium	EFDEGÉ, Solution injectable
Czech Republic	EFDEGE, injekční roztok
Germany	EFDEGE Injektionslösung
Greece	EFDEGE, Ενέσιμο διάλυμα για έγχυση 1GBq/mL
Hungary	EFDEGE injekciós oldat
Italy	EFDEGE Soluzione iniettabile
Luxembourg	EFDEGÉ, solution injectable
Malta	EFDEFGE, solution for injection
Netherlands	EFDEGE, oplossing voor injectie 1 GBq/mL
Poland	EFDEGE 1 GBq/ml roztwór do wstrzykiwań
Portugal	EFDEGE, solução injectável
Slovenia	EFDEGE raztopina za injiciranje

This leaflet was last approved in: 02/2015

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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The following information is intended for medical or healthcare professionals only:
The complete SmPC of EFDEGE is provided as a separate document 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)