Package leaflet: Information for the patient

Fludeoxyglucose (^{18}F) Synektik 200-2200 MBq/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 you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Fludeoxyglucose (^{18}F) Synektik is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance contained in Fludeoxyglucose (^{18}F) Synektik is fludeoxyglucose (^{18}F) and is designed for the capture of diagnostic images of some parts of your body.

Once a small amount of Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik is used

Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik :

- 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 Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik
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.

Fludeoxyglucose (^{18}F) Synektik with food and drink
You should be fasting for at least 4 hours before the administration of the product. You should drink plenty of water and avoid drinking liquids containing sugar.

Your 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 Fludeoxyglucose (^{18}F) Synektik 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 duringpregnancy 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 doctor 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 Fludeoxyglucose (^{18}F) Synektik will affect your ability to drive or to use machines.

Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik will be used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik and conduct of the procedure
Fludeoxyglucose (^{18}F) Synektik 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. Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik, 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 given more Fludeoxyglucose (^{18}F) Synektik than you should
An overdose is unlikely because you will only receive a single dose of Fludeoxyglucose (^{18}F) Synektik precisely controlled by the 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 that you drink abundantly in order to facilitate the elimination of Fludeoxyglucose (^{18}F) Synektik 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 Fludeoxyglucose (^{18}F) Synektik, please ask your nuclear medicine doctor who supervises the procedure.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

This radiopharmaceutical product will deliver low amount of ionising radiation with the 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.

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

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

5. How Fludeoxyglucose (^{18}F) Synektik 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.

6. Contents of the pack and other information

What Fludeoxyglucose (^{18}F) Synektik contains
- The active substance is Fludeoxyglucose (^{18}F). 1 ml solution for injection contains 200-2200 MBq fludeoxyglucose (^{18}F) at the date and time of calibration.
- The other ingredients are: sodium chloride, water for injection, sodium acid citrate and sodium citrate.

What Fludeoxyglucose (^{18}F) Synektik looks like and contents of the pack
The activity per vial ranges from 40 MBq to 22000 MBq at the date and time of calibration.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

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The following information is intended for medical or healthcare professionals only:
The complete SmPC of Fludeoxyglucose (^{18}F) Synektik 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)