Package leaflet: Information for the patient

<Invented name> 1 GBq/mL solution for injection

fluorocholine (^{18}F) chloride

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. See section 4.

What is in this leaflet:

1. What <Invented name> is and what it is used for
2. What you need to know before <Invented name> is used
3. How <Invented name> is used
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only, which is used in Positron Emission Tomography (PET) examinations and is administered prior to such an examination.

The following indications for PET with <Invented name> have been sufficiently documented: prostate cancer and hepatocellular carcinoma.

The radioactive ingredient in <Invented name> allows to picture an enhanced influx of the natural substance choline in specific organs or tissues and is detected by PET and shown as a picture.

Positron Emission Tomography is an imaging technology used in nuclear medicine that produces pictures of cross-sections of living organisms. It works with a minute amount of radioactive pharmaceutical to produce quantitative and precise images of specific metabolic processes in the body. This examination is carried out to help decide on how to treat the illness you are suffering from or you are suspected of suffering from.
The use of <Invented name> does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceuticals outweighs the risk due to radiation.

2. What you need to know before <Invented name> is used

<Invented name> must not be used
- if you are allergic to fluorocholine (^{18}F) chloride or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant.

Warnings and precautions
Talk to your nuclear medicine doctor before you are administered **<Invented name>**:
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding

- if your kidneys do not function properly: in this case a very careful indication is required since you may be exposed to increased radiation.
- if you come into contact with infants: It is recommended to avoid close contact between the patient and infants in the 12 hours following the injection.

Before administration of <Invented name> 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.
- be fasting for at least 4 hours

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and <Invented name>
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: in particular if you are treated or have been treated by anti-androgen therapy, antimitotic chemotherapy (colchicine or other) or Hematopoietic (colony-)stimulating factors (CSF).

If you are in doubt, ask your nuclear medicine doctor who is carrying out the PET examination for further information.

<Invented name> with food and drink
You should be fasting for at least 4 hours before the administration of **<Invented name>**. However, you should drink plenty of water before and after the examination.

Pregnancy and breast-feeding
You must inform the nuclear medicine doctor before the administration 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 nuclear medicine doctor who will supervise the procedure.

<u>If you are pregnant</u>
This medicinal product must not be given to you during pregnancy.

<u>If you are breast-feeding</u>
If administration during breast-feeding is unavoidable, breast milk may be drawn off before injection and stored for subsequent use. Breast-feeding should be stopped for at least 12 hours. Any milk produced during this period should be discarded.
Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
The effects on the ability to drive and use machines have not been investigated.

<Invented name> contains sodium
According to the time of preparation of the 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 patients on low sodium diet.

3. How <Invented name> is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products.
<Invented name> 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 <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 140 to 280 MBq (depending on the patient's body mass, the type of camera used and the acquisition mode).

MegaBecquerel (MBq) is the unit used to express radioactivity.

Use in children and adolescents
Use in oncologic paediatrics is not recommended.

Administration of <Invented name> and conduct of the procedure
<Invented name> is administered by intravenous injection.
One injection is sufficient to conduct the test that your doctor needs.
After injection, you will be offered a drink and asked to urinate immediately preceding the test.

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

After administration of <Invented name>, 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

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more <Invented name> than you should
An overdose is unlikely because you will only receive a single dose of <Invented name> 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 <Invented name> from your body (indeed the principle way of elimination of this medicine is renal, in the urine).

It may become necessary to take diuretics.

Should you have any further question on the use of <Invented name>, 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.
No adverse effects have been observed to date.

This radiopharmaceutical will deliver low amounts of ionising radiation associated 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.

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 listed in Appendix V .

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

You will not have to store <Invented name>. This medicine 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 "EXP".

6. Contents of the pack and other information

What <Invented name> contains
- The active substance is: fluoromethyl-(^{18}F)-dimethyl-2-hydroxyethyl-ammonium chloride (or fluorocholine (^{18}F) chloride).
- 1 mL solution for injection contains 1 GBq = 1 000 MBq fluorocholine (^{18}F) chloride at the date and time of calibration
- The other ingredients are: sodium chloride and water for injections.

What <Invented name> looks like and contents of the pack
You do not have to obtain the medicine yourself, nor do you have to handle the packaging or the vial. The following is for your information only.

<Invented name> is a clear and colourless liquid.

The activity per vial ranges from 500 MBq to 15 000 MBq at the date and time of calibration.

Marketing Authorisation Holder

SYNEKTIK S.A.
ul. Józefa Piusa Dziekońskiego 3
00-728 Warsaw
Poland

Manufacturer

Synektik Pharma Sp. z o.o.
ul.Szaserów 128
04-349 Warsaw
Poland

Synektik Pharma Sp. z o.o.
ul. Artwińskiego 3
25-734 Kielce
Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Lithuania	FLUOROCHOLINE (^{18}F) SYNEKTIK 1 GBq/ml injekcinis tirpalas
Poland	FLUOROCHOLINE (^{18}F) SYNEKTIK
Czech Republic	Fluorocholine (^{18}F) Synektik
Slovak Republic	FLUOROCHOLINE (^{18}F) SYNEKTIK 1 GBq/mL, injekčný roztok

This leaflet was last revised in [To be completed nationally]

Detailed information on this medicine is available on the website of the Medicines Agency web site: {name and website of the Member state Agency}.

The following information is intended for medical or healthcare professionals only:
The complete SmPC of **<Invented name>** 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)