PACKAGE INSERT: INFORMATION FOR PATIENTS

FLT(^{18}F) Synektik, 1000 MBq/ml, solution for injection
fluorodeoxythymidine (^{18}F)

Read this leaflet carefully before use as it contains important information for the patient.

- Keep this leaflet so that you can read it again if necessary.
- If in any doubt, ask the nuclear medicine specialist supervising the study.
- If you experience any side effects, including any side effects not listed in this leaflet, tell your nuclear medicine specialist. See section 4.

Table of contents of the leaflet:

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

This medicine is intended for diagnostic purposes only.

FLT (^{18}F) Synektik is intended for determining the location of malignant tumours, thanks to its ability to mark cells in which very intense processes of division take place.

The drug FLT (^{18}F) Synektik contains the radioactive substance, fluorodeoxytymidine (^{18}F) , and is used in *positron emission tomography* (PET) examinations. The drug FLT (^{18}F) Synektik is administered before the examination.

After a small amount of FLT (^{18}F) Synektik has been administered, the doctor will take images with a special camera (CT scanner), from which the patient's condition and disease progress will be assessed.

The doctor will only administer the drug if the clinical benefits of the radiopharmaceutical outweigh the risks associated with the patient's exposure to ionising radiation.

2. Important information before using FLT (^{18}F) Synektik

When not to use FLT (^{18}F) Synektik
- If the patient is allergic to fluorodeoxythymidine (^{18}F) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Special care should be taken with FLT(^{18}F) Synektik:

- if the patient is pregnant or thinks she may be pregnant;
- if the patient is breast-feeding;
- if the patient's kidneys are not functioning properly; in this case, very careful consideration of the indication for the test is required as the patient may be exposed to increased radiation;

Prior to administration of FLT (^{18}F) Synektik:

- the patient will be advised by the physician to drink a lot and urinate frequently.

After administration of FLT (^{18}F) Synektik:

- during the first 12 hours after injection, the patient is advised to avoid close contact with young children and pregnant women.

Children and adolescents
This medicine is intended for adult patients only.

FLT (^{18}F) Synektik and other medicines
Tell your nuclear medicine specialist about all medicines you are currently or recently taking and any medicines you plan to take, as other medicines may affect the evaluation of the test results.

FLT (^{18}F) Synektik with food and drink
There are no known restrictions on the type of food and drink consumed.

Pregnancy and breast-feeding
If the patient is pregnant or breastfeeding, suspects she may be pregnant or if she is planning a pregnancy,
should consult a nuclear medicine physician before using this medicine.

Pregnant patients
The nuclear medicine physician will decide on the use of FLT (^{18}F) Synektik in women with a positive pregnancy test only if the expected benefit to the woman from the administration of this drug outweighs the risk to the foetus associated with the administration of the drug. If the estimated dose to the foetus is less than 1 mSv, administration of the radiopharmaceutical is acceptable when justified.

Breast-feeding patients
After injection of FLT (^{18}F) Synektik, breastfeeding should be interrupted for 12 hours and any breast milk pumped during this time should be removed.
The resumption of breastfeeding should be agreed with the nuclear medicine specialist who will perform the study. Before administering the radiopharmaceutical, an adequate amount of milk can be pumped and stored for later use.

Breastfeeding women are advised to avoid close contact with young children for 12 hours after fluorodeoxythymidine (^{18}F) administration.

Driving and using machines
FLT(^{18}F) Synektik has no or negligible effect on the ability to drive and operate machinery.

FLT(^{18}F) Synektik contains sodium.
This medicine, in a maximum dose of 10 ml, may contain no more than 33.5 mg of sodium, which corresponds to 1.7% of the WHO recommended maximum daily dose of sodium in adults (2g). This should be taken into account for patients on a low-sodium diet.

FLT (^{18}F) Synektik contains ethanol
This medicine at the maximum dose (10 ml) contains 790 mg of alcohol (ethanol), equivalent to 20 ml of beer

or 8 ml of wine.
The small amount of alcohol in this medicine will not cause noticeable effects.

3. How to use the drug FLT (^{18}F) Synektik

The use, handling and disposal of radiopharmaceutical products are strictly regulated. The drug FLT (^{18}F) Synektik will only be used in specially controlled rooms and administered to patients in accordance with the principles of radiological protection by trained and qualified medical professionals. These professionals will rigorously follow the rules for the safe use of the drug and inform the patient about the activities performed.

The nuclear medicine specialist supervising the study will select the appropriate dose of FLT (^{18}F) Synektik drug for each patient. This will be the smallest amount of drug to allow the study to be performed.
The recommended activity for an adult patient weighing 70 kg, is between 150 and 600 MBq of fludeoxytimidine (^{18}F) (the dose should be selected individually according to body weight and/or depending on the type of imaging technique used, the clinical picture, the patient's condition and the information gathered during the history).

Administration of FLT (^{18}F) Synektik and conduct of the study
The medicinal product FLT (^{18}F) Synektik is administered by direct intravenous injection. The test is performed 15-30 minutes after intravenous administration.

Prior to administration, the patient will be advised by the physician to drink a lot and urinate frequently. This is to reduce exposure of the urinary system to the harmful effects of radiation.

Duration of the examination
The nuclear medicine specialist will inform the patient how long the test will take.

After administration of FLT (^{18}F) Synektik, you should:
- avoid close contact with young children and pregnant women for 12 hours after the injection;
- urinate frequently to accelerate the removal of the drug from the patient's body.

The nuclear medicine specialist will provide the patient with appropriate information on special recommendations for post-drug management, if necessary.
Taking more than the recommended dose of FLT (^{18}F) Synektik
This medicine is administered under the close supervision of a nuclear medicine physician, so an overdose is very unlikely. However, if an overdose does occur, the patient will receive appropriate treatment.

If you have any further questions about the use of the medicine, please ask the nuclear medicine specialist who will be supervising the study.

4. Possible side effects

Like any medicine, this medicine may cause side effects, although not everyone will experience them. FLT (^{18}F) Synektik emits a small amount of radioactivity, which is associated with a low risk of cancer and birth defects.

Reporting of side effects
If you experience any side effects, including any side effects not listed in the leaflet, tell your nuclear medicine specialist.

Adverse reactions can be reported directly to the Adverse Drug Reactions Monitoring Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

Al. Jerozolimskie 181C
02-222 Warsaw
Tel: +48 22 49 21 301
Fax: +48 22 49 21 309
Website: https://smz.ezdrowie.gov.pl

Side effects can also be reported to the responsible entity.

By reporting side effects, more information can be gathered on the
the safety of the medicine.

5. How to store the drug FLT (^{18}F) Synektik

The patient will not store this medicine. Radiopharmaceuticals are stored according to
according to national regulations for radioactive materials.

The information below is intended for professional medical personnel only. Store below 25°C. Do not freeze.

Expiry date: 14 hours after completion of synthesis.
After first use, store below 25°C and use within 8 hours, not exceeding the expiry date stated on the label.
not exceeding the expiry date stated on the label.

Do not use this medicine after the expiry date which is stated on the label after: Expiry
date (EXP) :{DD MM YYYY HH:MM}.

Use only clear solution containing no visible particles.

6. Package contents and other information

What does the drug FLT (^{18}F) Synektik contain?

1 vial contains:
Active substance: fludeoxytimidine (^{18}F) 1000 MBq/ml per day and calibration hour.
Excipients: water for injection, citrate buffer* pH 5.2, ethanol.
*disodium hydrogen citrate, sodium citrate, hydrochloric acid, water for injection, sodium chloride.

What FLT ($^{(18)\,F}$) Synektik looks like and what it contains in the package

FLT (^{18}F) Synektik is a clear, colourless or yellow solution with no visible particles. The 25 ml multi-dose vial is made of colourless type I glass, closed with a bromobutyl rubber stopper and secured with an aluminium ring.
The vial contains 1 ml to 20 ml of solution, corresponding to an activity of 1,000 to 20,000 MBq /vial per day and calibration hour.

Expiry date (EXP)
Batch number (Lot)

Responsible party and manufacturer

Responsible company
Synektik Pharma Sp. z o.o.
ul. Józefa Piusa Dziekońskiego 3
00-728 Warsaw Poland
e-mail:synektikpharma@synektik.com.pl

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

Date of last revision of the leaflet: 03/2023

Detailed information on this medicine is available on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products: https://www.urpl.gov.pl.

Information intended for professional medical personnel only:

In order to provide professional medical personnel with additional scientific and practical information on the administration and use of this radiopharmaceutical product, the full Summary of Product Characteristics (SmPC) of FLT(^{18}F) Synektik is included in the package.