PACKAGE LEAFLET

Package leaflet: Information for the patient

<Invented name> 2.0 GBq/mL, solution for injection
Sodium fluoride (^{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. See section 4.

What is in this leaflet:

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

<Invented name> contains the active substance sodium fluoride (^{18}F).
This medicine is a radiopharmaceutical product (radioactive medicine) for diagnostic use only.
<Invented name> is used for diagnosis in Positron Emission Tomography (PET) examinations and is administered prior to such an examination.

The radioactive substance in <Invented name> (to show bone metabolism) is detected by PET and is 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 nuclear medicine doctor will have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

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

<Invented name> must not be administered
- if you are allergic (hypersensitive) to sodium fluoride (^{18}F) or any of the other ingredients of <Invented name> listed in section 6.
- if you are pregnant or think you may be pregnant inform your nuclear medicine doctor.

Warnings and precautions
Take special care with <Invented name>

Inform your nuclear medicine doctor before <Invented name> is administered in the following cases:
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding
- if you have kidney problems

Before <Invented name> administration you should
- Drink plenty of water and be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study

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

Other medicines and <Invented name>
Tell to your nuclear medicine doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription since they may interfere with the acquisition of the images.

Pregnancy and breast-feeding
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 taking this medicine.

If you are pregnant
<Invented name> must not be administered to you.

You must inform the nuclear medicine doctor before the administration of <Invented name> if there is a possibility you might be pregnant or if you have missed your period.
When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are breast-feeding, 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.
It is recommended that you avoid close contact with infants in the initial 12 hours following the injection.

Driving and using machines
It is considered unlikely that <Invented name> will affect your ability to drive or to use machinery.

<Invented name> contains sodium
This product may contain more than 1 mmol of sodium (up to 23 mg per dose), this should be taken into account if you are with a low sodium diet.

3. How <Invented name> is administered

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.

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 usual amount recommended for an adult is 100-400 MBq. Megabecquerel (MBq) is the unit used to express radioactivity.

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the body mass.

Administration of <Invented name> and conduct of the procedure
<Invented name> is administered by single intravenous injection.

Duration of the procedure
Your nuclear medicine doctor supervising the procedure will inform you about the usual duration of the procedure. A PET examination is usually taken about 60 minutes and up to 3 hours after the injection, depending on the procedure.
After injection, you will be offered a drink and asked to urinate immediately preceding the test.

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
- if you come into contact with infants: It is recommended that close contact be avoided between the patient and infants in the initial 12 hours following the injection.

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 almost impossible 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. The elimination of the radioactive constituents should be increased as much as possible. You should drink as much as possible and frequently empty your bladder. It may become necessary to take diuretics. If you have any further question on the administration of <Invented name> , please ask your nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, <Invented name> can cause side effects, although not everybody gets them.
No serious adverse effects have been observed to date.

This administered radiopharmaceutical will deliver low amounts of ionising radiation with very low risk of cancer and hereditary abnormalities.

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 <Invented name> is stored

You will not have to store this medicine. 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.
<Invented name> must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What <Invented name> contains
- The active substance is sodium fluoride (^{18}F). One mL contains 2.0 GBq of sodium fluoride (^{18}F) at date and time of calibration.
- The other ingredients are water for injections, sodium chloride and potassium dihydrogen phosphate.

What <Invented name> looks like and contents of the pack

Colourless solution in 15 or 25 mL multidose vial.
The total activity of the vial at that time is therefore between 0.4 GBq and 44.0 GBq.

Marketing Authorisation Holder

SYNEKTIK S.A.
ul. Józefa Piusa Dziekońskiego 3
00-720 Warsaw
Poland

Manufacturer

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

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

Poland	Natrii fluoridum (^{18}F) Synektik
Lithuania	Natrii fluoridum (^{18}F) Synektik 2,0 GBq/mL, injekcinis tirpalas
Slovak Republik	METAFLU 2,0 GBq/mL, injekčný roztok

This leaflet was last revised in {MM/YYYY} {month YYYY}.

Other sources of information

Detailed information on this medicine is available on the {member state medicines agency} web site: http://www.{ }.

The following information is intended for 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).