

**PACKAGE LEAFLET**  
**Package leaflet: Information for the patient**

**Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska, 450 - 11250 MBq/mL, solution for injection**

fludeoxyglucose ( $^{18}\text{F}$ )

**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 Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is and what it is used for
2. What you need to know before you use Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska
3. How Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is used
4. Possible side effects
5. How to store Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska
6. Contents of the pack and other information

**1. What Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is and what it is used for**

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance contained in Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is fludeoxyglucose ( $^{18}\text{F}$ ). It is designed for the capture of diagnostic images of some parts of your body.

Once a small amount of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska has been injected, medical images that are obtained with a special camera (a so-called PET 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 you use Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska**

**Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska must not be used**

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

**Warnings and precautions**

Talk to your doctor before you are given Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska:

- if you are a diabetic and your diabetes is currently not controlled
- if you have an infection or an inflammatory disease
- if you have kidney problems

Inform your doctor beforehand in the following cases:

- if you are pregnant or think you might be pregnant
- if you are breast-feeding.

**Before administration of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska 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 injection
- avoid all strenuous physical activity
- be fasting for at least 4 hours.

### **Children and adolescents**

Talk to your doctor if you are under 18 years old.

### **Other medicines and Fludeoxyglucose (<sup>18</sup>F) Karolinska**

Tell your 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, particularly:

- any medicine that may cause a change in your blood sugar, such as medicines that
  - o reduce inflammation (e.g. corticosteroids),
  - o prevent convulsions (e.g. valproate, carbamazepine, phenytoin, phenobarbital),
  - o affect the nervous system (e.g. adrenaline, noradrenaline, dopamine, etc.),
- glucose,
- insulin,
- medicines used to increase the production of blood cells.

### **Fludeoxyglucose (<sup>18</sup>F) Karolinska with food and drink**

A high blood glucose concentration (hyperglycaemia) can make the doctor's interpretation of the images more difficult. Therefore:

- you should be fasting for at least 4 hours before you are given the injection.
- you should drink plenty of water.
- you should avoid drinking liquids containing sugar.

Your doctor will check your blood sugar level before giving you Fludeoxyglucose (<sup>18</sup>F) Karolinska.

### **Pregnancy and breast-feeding**

You must tell your doctor before the administration of Fludeoxyglucose (<sup>18</sup>F) Karolinska if there is a possibility that you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult the doctor who will supervise the procedure.

### **If you are pregnant**

Your doctor will only administer this product during pregnancy if the benefit is considered to outweigh the risks.

### **If you are breast-feeding**

You must stop breast-feeding for 12 hours after the injection and the maternal milk must be pumped and discarded.

Check with your doctor when you should restart breast-feeding.

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

### **Driving and using machines**

It is unlikely that Fludeoxyglucose (<sup>18</sup>F) Karolinska will affect your ability to drive or to use machines.

### **Fludeoxyglucose (<sup>18</sup>F) Karolinska 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. If in doubt, talk to the doctor supervising the examination.

### **Fludeoxyglucose (<sup>18</sup>F) Karolinska contains ethanol**

This medicine contains up to 50 mg of alcohol (ethanol) in each vial which is equivalent to 4.167 mg/mL.

The amount in one vial of this medicine is equivalent to less than 2 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

## **3. How Fludeoxyglucose (<sup>18</sup>F) Karolinska is used**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Fludeoxyglucose (<sup>18</sup>F) Karolinska will only be used in a hospital/clinic, in special controlled areas. This product will only be handled and given to you by staff who are trained and qualified to use it safely.

These persons will make sure the product is used safely and will tell you what they are doing during your examination procedure.

The doctor supervising the procedure will decide on the quantity of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska to be used in your case. It will be the smallest quantity necessary to get the desired information.

The usual amount an adult will be given ranges from 100 to 400 MBq (depending on the patient's body mass, the type of camera used for imaging and the acquisition mode). Mega Becquerel (MBq) is a unit to express radioactivity.

#### **Use in children and adolescents**

The quantity to be given to a child or adolescent will depend on their weight.

#### **Administration of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska and conduct of the procedure**

Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is given as a single injection into a vein.

One injection is enough for the test that your doctor needs.

After injection you will need to remain completely at rest, without reading or talking. You will be offered a drink and asked to urinate immediately before the test.

During the test, you will need to be completely at rest, lying down comfortably. You should not move or talk.

#### **Duration of the procedure**

Your doctor will tell you how long the test will last.

Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska will be given 45-60 minutes before the test takes place.

The test usually lasts 30 to 60 minutes.

#### **After administration of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska you should:**

- avoid any close contact with young children and pregnant women for the 12 hours after the injection
- urinate frequently to remove the Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska from your body

#### **If you have been given more Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska than intended**

An overdose is unlikely because you will only receive a single dose of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska precisely controlled by the doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. The doctor in charge of the procedure may recommend that you drink a lot to get rid of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska 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 ( $^{18}\text{F}$ ) Karolinska, please ask your doctor.

### **4. Possible side effects**

Like all medicines, Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska can cause side effects although not everybody gets them.

Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska will deliver a low amount of ionising radiation with very low risk of causing cancer and hereditary abnormalities.

Your doctor has considered that the clinical benefit that you will obtain from the test with Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska overcomes the risk due to radiation.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

### **5. How to store Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska**

You will not have to store this product yourself. The product is stored under the responsibility of the specialist in the hospital. Storage of Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska will be in accordance with national regulations on radioactive materials.

**The following information is intended for the specialist only.**

Store below 25°C. Store in original vial . Store in or behind lead shielding.

Do not use this medicine after the expiry date and time which is stated on the label.

## **6. Contents of the pack and other information**

### **What Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska contains**

- The active substance is fludeoxyglucose ( $^{18}\text{F}$ ). 1 mL solution for injection contains 450 - 11250 MBq fludeoxyglucose ( $^{18}\text{F}$ ) at the date and time of calibration.
- The other ingredients are sodium chloride, sodium citrate, disodium hydrogen citrate and water for injection.

### **What Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska looks like and contents of the pack**

Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is a clear and colourless, or slightly yellow, solution for injection.

Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska is delivered in a colourless glass multidose vial containing up to 12 mL solution, with a radioactivity concentration of 450 - 11250 MBq/mL at the date and time of calibration.

### **Marketing Authorisation Holder**

[To be completed nationally]

### **Manufacturer**

[To be completed nationally]

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

|            |                                                |
|------------|------------------------------------------------|
| Sweden:    | Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska |
| Estonia:   | Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska |
| Latvia:    | Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska |
| Lithuania: | Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska |
| Norway:    | Fludeoxyglucose ( $^{18}\text{F}$ ) Karolinska |

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