

## **Package leaflet: Information for the patient**

### **Fludeoxyglucose (<sup>18</sup>F) Monrol 200-2200 MBq/ml solution for injection** Fludeoxyglucose (<sup>18</sup>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 (<sup>18</sup>F) Monrol is and what it is used for
2. What you need to know before you use Fludeoxyglucose (<sup>18</sup>F) Monrol
3. How to use Fludeoxyglucose (<sup>18</sup>F) Monrol
4. Possible side effects
5. How to store Fludeoxyglucose (<sup>18</sup>F) Monrol
6. Contents of the pack and other information

#### **1. What Fludeoxyglucose (<sup>18</sup>F) Monrol is and what it is used for**

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance contained in Fludeoxyglucose (<sup>18</sup>F) Monrol is fludeoxyglucose (<sup>18</sup>F) and is designed for the capture of diagnostic images of some parts of your body.

Once a small amount of Fludeoxyglucose (<sup>18</sup>F) Monrol 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 you use Fludeoxyglucose (<sup>18</sup>F) Monrol**

##### **Do not use Fludeoxyglucose (<sup>18</sup>F) Monrol**

- if you are allergic to fludeoxyglucose (<sup>18</sup>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 (<sup>18</sup>F) Monrol:

- 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 (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol**

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 (<sup>18</sup>F) Monrol with food and drink**

You should be fasting for at least 4 hours before the administration of the medicinal 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 medicinal product; indeed a high blood glucose concentration (hyperglycaemia) can make the nuclear medicine doctor's interpretation more difficult.

**Pregnancy, breast-feeding and fertility**

You must inform the nuclear medicine doctor before the administration of Fludeoxyglucose (<sup>18</sup>F) Monrol 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 medicine doctor will only administer this medicinal product during pregnancy 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 (<sup>18</sup>F) Monrol will affect your ability to drive or to use machines.

### **Fludeoxyglucose (<sup>18</sup>F) Monrol contains sodium**

This medicine contains 29 mg sodium (main component of cooking/table salt) in each dosage unit. This is equivalent to 1.5 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to use Fludeoxyglucose (<sup>18</sup>F) Monrol**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Fludeoxyglucose (<sup>18</sup>F) Monrol will only be used in special controlled areas. This medicinal 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 medicinal product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Fludeoxyglucose (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol and conduct of the procedure**

Fludeoxyglucose (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol, 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 use more Fludeoxyglucose (<sup>18</sup>F) Monrol than you should**

An overdose is unlikely because you will only receive a single dose of Fludeoxyglucose (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol 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 (<sup>18</sup>F) Monrol, 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 to store Fludeoxyglucose (<sup>18</sup>F) Monrol**

You will not have to store this medicinal product. This medicinal product is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals products will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

This medicinal 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 (<sup>18</sup>F) Monrol contains**

- The active substance is Fludeoxyglucose (<sup>18</sup>F). 1 ml solution for injection contains 200-2200 MBq fludeoxyglucose (<sup>18</sup>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 (<sup>18</sup>F) Monrol looks like and contents of the pack**

Fludeoxyglucose (<sup>18</sup>F) Monrol is available in multidose vial, closed by natural rubber closure and sealed by an aluminum capsule. One vial contains 0.2 to 15 mL of solution, corresponding to 40 - 33000 MBq at calibration time.

#### **Marketing Authorization Holder and Manufacturer**

##### **Marketing Authorization Holder**

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**This leaflet was last revised in ....**

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The following information is intended for medical or healthcare professionals only:  
The complete SmPC of Fludeoxyglucose (<sup>18</sup>F) Monrol is provided as a separate document in the medicinal 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).