

PACKAGE LEAFLET: INFORMATION FOR THE USER

GLUSCAN, 600 MBq/mL, Solution for injection Fludeoxyglucose (¹⁸F)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What GLUSCAN is and what it is used for
2. Before you use GLUSCAN
3. How to use GLUSCAN
4. Possible side effects
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6. Further information

1. WHAT GLUSCAN IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for diagnostic use only.

The active ingredient contained in GLUSCAN is designed for the capture of radiographical images of some parts of your body.

Once a small amount of GLUSCAN has been injected, a medical test will enable the physician to capture images and to ascertain the localisation or the evolution of your disease.

2. BEFORE YOU USE GLUSCAN

Do not use GLUSCAN

- if you are allergic (hypersensitive) to fludeoxyglucose (¹⁸F) or any of the other ingredients of GLUSCAN,
- if you are pregnant.

Take special care with GLUSCAN

Inform the physician conducting the test in the following cases:

- if you have non equilibrated diabetes,
- if you are breast-feeding,
- if you have an infection or an inflammatory disease,
- if you are under 18 years old,
- if you are affected by renal disorders.

Before the test you should:

- avoid all important physical activity,
- drink abundantly during the 4 hours preceding the test (non sugar containing beverages),
- be fasting for at least 4 hours.

After the administration of this product, you should avoid any close contact with young children for 12 hours following the injection.

After the test, you shall urinate frequently in order to eliminate the product from your body.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. GLUSCAN 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.

Using other medicines

Please tell your physician if you are taking, or have been administered any of the following substances, since they may interfere with your physician interpretation of the images:

- any medicine that may induce a modification of the blood sugar rate (glycemia), such as drugs having an effect on inflammation (corticosteroids), drugs against convulsions (valproate, carbamazepine, phetytoin, phenobarbital), drugs affecting the nervous system (adrenalin, noradrenalin, dopamin...),
- glucose,
- insulin,
- factors increasing the production of blood cells.

Please tell your doctor or your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using GLUSCAN with food and drink

This medicine can only be injected in patients who have been fasting for at least 4 hours.

The blood sugar rate (glycemia) is to be measured before administering the medication; indeed a high blood sugar rate (hyperglycemia) can make the physician's interpretation more difficult.

Pregnancy and breast-feeding

You must inform your physician if there is a possibility you might be pregnant, if you have not had your last period or if you are breast-feeding.

When in doubt, it is important to consult your physician.

Your physician will only consider this test during your pregnancy in case of absolute necessity.

If you are breast-feeding, you must stop breast-feeding for 12 hours after the injection and the maternal milk pumped must be discarded. During that period, you should replace maternal milk with a substitution one and avoid close contact with your infant.

Resuming breast-feeding should be in agreement with your physician.

Please ask your doctor or your pharmacist before taking any medicines.

Driving and using machines

The effects on aptitude to drive vehicles and use machines were not studied.

However, it is considered unlikely that GLUSCAN will affect your ability to drive or to operate machinery.

3. HOW TO USE GLUSCAN

Dosage

The qualified physician, in charge of conducting the test, will ascertain the quantity of GLUSCAN to be used in your case. It will be the minimal quantity necessary to acquire images which will give the desired information about your disease.

The amount to be administered usually recommended for an adult ranges from 200 to 500 MBq (depending on the patient's corporal mass and the type of camera used).

In children, the quantity to be administered will be adapted to his/her corporal mass.

Method and route of administration

GLUSCAN is administered intravenously.

Before the product injection, avoid any important physical activity.

After injection, you will be offered a drink and asked to urinate immediately preceding the test.

During the test, you will need to be completely at rest, comfortably lying down, without reading nor talking.

Frequency of administration

One injection is sufficient to conduct the test that your physician needs.

If you are being treated by radiotherapy, the test conducted with GLUSCAN should be delayed for 4 months after the last session.

If you are being treated by chemotherapy, the test conducted with GLUSCAN should be delayed for 4 to 6 weeks after the last administration.

Treatment duration

Your physician will inform you of the exact length of the test.

Generally speaking, GLUSCAN is administered as a single injection in a vein, one hour before the test takes place. The test lasts 30 to 60 minutes.

If you have been administered more GLUSCAN than you should

An overdose is almost impossible because you will only receive a single dose of GLUSCAN precisely prepared and controlled by your physician. However, in the case of an overdose, you will receive the appropriate treatment from your physician. In particular, your physician may recommend that you drink abundantly in order to facilitate the elimination of GLUSCAN from your organism (indeed the principle way of elimination of this medicine is renal, in the urine).

Should you have any further question on the use of GLUSCAN, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, GLUSCAN may cause side effects, although none has been observed as of this day.

If you notice any side effects, please tell your doctor or pharmacist.

5 HOW TO STORE GLUSCAN

This product is stored at the hospital. Indeed specific care should be taken due to radioactivity.

This product should be stored in its original packaging, not above 25°C.

6. FURTHER INFORMATION

What GLUSCAN contains

1mL of GLUSCAN contains:

- Active substance: 600MBq of fludeoxyglucose (¹⁸F)
- Other ingredients: water for injection, sodium chloride 0.9%.

What GLUSCAN looks like and contents of the pack

GLUSCAN is a solution for injection which is clear, colourless or slightly yellow.

The outer packaging contains a lead shielding for protection against ionizing radiations, inside this lead container stands a 10 mL glass vial containing GLUSCAN solution for injection.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Belgium: GLUSCAN

France: GLUSCAN

Italy: GLUSCAN

Luxembourg: GLUSCAN

This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the web site of the French Health Products Safety Agency (<http://afssaps.sante.fr>).