

Erigal

Fludeoxyglucose (^{18}F) Injection, Erigal.

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Read all of this leaflet carefully before you are administered this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or the specialist physician in Nuclear Medicine who will supervise the procedure.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your referring doctor or the specialist physician in Nuclear Medicine who has supervised the procedure.

In this leaflet:

1. What Fludeoxyglucose Erigal* is and what it is used for.
2. Before Fludeoxyglucose Erigal is administered.
3. How Fludeoxyglucose Erigal will be used.
4. Possible side effects.
5. How to store Fludeoxyglucose Erigal.
6. Further information.

1. What Fludeoxyglucose Erigal is and what it is used for.

What Fludeoxyglucose Erigal is:

Fludeoxyglucose Erigal is a type of medicine called a diagnostic radiopharmaceutical medicine. It is used to help identify (diagnose) and pinpoint (localise) the illness you may have.

What Fludeoxyglucose Erigal is used for:

Fludeoxyglucose Erigal is used to help diagnose and locate certain types of medical illnesses, including brain problems, heart problems, cancer, infections and inflammatory illnesses.

Fludeoxyglucose Erigal consists of a sugar called deoxyglucose that is attached to a tiny amount of a radioactive substance, known as Fluorine-18, to form a substance called Fludeoxyglucose 18F.

Your body contains millions of living cells. All the cells use sugar (glucose) for energy. When you have certain medical conditions, some parts of your body will use more glucose than normal. Doctors use this change in the amount of glucose used to help identify and pinpoint the site of certain medical conditions.

When Fludeoxyglucose Erigal is given to you, a small amount of radioactive glucose spreads around your body and reaches the areas where glucose is being used the most.

By using a special camera, known as a PET scanner or a gamma-camera, pictures (images) of the radiation coming from the Fludeoxyglucose Erigal let your doctor 'see' where the radioactive glucose is being used the most. He/she can then use this to help identify (diagnose) and pinpoint sites where you have a particular medical condition.

This diagnostic medicine can be used to help find out:

- i. Whether you have certain brain conditions such as epilepsy, dementia (Alzheimer's), infections or tumours.
- ii. If you have an abnormality of the heart.
- iii. If you have a certain type of cancer and where it is located.
- iv. How well your cancer treatment is working.

2. Before Fludeoxyglucose Erigal is administered

Fludeoxyglucose Erigal must never be administered:

- if you are allergic (hypersensitive) to fludeoxyglucose (^{18}F) or any of the other ingredients of Fludeoxyglucose Erigal, (see section 6 for a list of ingredients).

Take special care with Fludeoxyglucose Erigal:

Tell your doctor or specialist:

- If you have diabetes. The test may not give the right result if you have high blood sugar. Also read the sections overleaf on using other medicines and using Fludeoxyglucose Erigal with food and drink.
- If you have an infection or an inflammatory disease.
- If you suffer from kidney problems.

Tell your doctor or the specialist in Nuclear Medicine:

- If you are pregnant or believe you may be pregnant.
- If you are under 18 years old.
- If you are breast-feeding. Your doctor or specialist will advise you what to do. Also read the section on pregnancy and breast feeding.

Using other medicines

Please tell your doctor or the specialist who will supervise the procedure if you are taking, or have recently taken, any other medicines, even those not from your doctor or specialist, such as treatments that you might buy in a pharmacy or in a supermarket, since they may interfere with the results of the tests, including:

- any medicine that may affect the level of glucose in your body, such as medicines that have an effect on inflammation (corticosteroids), medicines that are used to treat convulsions (valproate, carbamazepine, phenytoin, phenobarbital), and medicines that affect the nervous system (adrenaline, noradrenaline, dopamine), as well as glucose and insulin,
- any medicine that may increase the amount of blood cells in your body.

Using Fludeoxyglucose Erigal with food and drink:

Before receiving the medicine drink plenty of water during the 4 hours before you have the test.

This medicine can only be given to patients who have not eaten anything (been fasting) for at least 4 hours.

Your blood sugar level should be measured before you receive the medicine. If you have a high blood sugar level it will be difficult for the specialist to understand the results of the test.

All Patients Except Diabetics:

You should not eat for 4 hours before you receive the injection but you should continue to drink water (not tea, coffee or soft drinks). If you have had anything to eat or drink in the 4 hours before the injection (other than water) tell your specialist.

Diabetics:

If you are diabetic the specialist will tell you what you can eat and drink and when you should take your diabetic drugs so that the test will work. You should continue to drink water (not tea, coffee or soft drinks). The test may not give the right result if you have high blood glucose.

Pregnancy and breast-feeding

You must tell the specialist before the injection of Fludeoxyglucose Erigal if there is a possibility that you might be pregnant, if you have missed your period or if you are breast-feeding.

If you are pregnant:

This diagnostic test should not normally be used by pregnant women. Your doctor will only consider this examination during your pregnancy in case of absolute necessity. When in doubt, it is important to consult the specialist who will supervise the procedure.

If you are breast-feeding:

You will need to stop doing so for about 12 hours after receiving this radioactive medicine and any maternal milk pumped should be discarded. This is because it may harm your baby. A small amount of this radioactive medicine could get into your breast milk. Your doctor or specialist will advise you about when you can start breast-feeding again.

Ask your doctor or specialist who will advise you about taking any medicines.

Before Fludeoxyglucose Erigal administration you should:

- avoid physical activity
- drink plenty of water during the 4 hours before the test
- not eat anything for at least 4 hours.

After administration of Fludeoxyglucose Erigal has been performed, you should:

- Urinate frequently - this will help to remove Fludeoxyglucose Erigal from your body.

If you are looking after children you should not cuddle or hug them for about 12 hours after you have had the scan. This is because your body will still contain a small amount of radioactivity.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Fludeoxyglucose Erigal 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 to use the product safely and will keep you informed of their actions.

Driving and using machines

Fludeoxyglucose Erigal will not affect your ability to drive or to use machines.

Important information about some of the ingredients of Fludeoxyglucose Erigal

Fludeoxyglucose Erigal contains a sugar (glucose) attached to a tiny amount of a radioactive substance, known as Fluorine-18. This stops being radioactive after about 4 hours.

The dose of Fludeoxyglucose Erigal given to you may contain sodium at levels greater than 1 mmol (23 mg). This is important information for patients who are on a low sodium diet.

3. How will Fludeoxyglucose Erigal be used?

Fludeoxyglucose Erigal must be given to you by a qualified doctor or a person who is a specialist in handling radioactive medicines. This medicine is injected into one of your blood vessels (a vein) using a needle and syringe.

The doctor or specialist supervising the procedure will decide on the amount of Fludeoxyglucose Erigal needed for the test. It will be the smallest amount needed to obtain a result.

The amount of Fludeoxyglucose Erigal that you receive for the test will be carefully worked out. The medicine is made just for you and contains the right amount of radioactivity that will give clear pictures (images).

The recommended dose for an adult ranges from 100 to 400 MBq (depending on your body mass, the type of camera used for imaging and the way in which the images are taken). A megabecquerel (MBq) is a metric measurement unit of radioactivity.

Use in children

In case of use in children, the quantity to be administered will be adapted to the child's body mass

Administration of Fludeoxyglucose Erigal and conduct of the procedure

Fludeoxyglucose Erigal is administered intravenously.

One injection is sufficient to conduct the test that your physician needs. After injection, 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, without reading or talking.**

Duration of the procedure:

Your doctor or specialist will inform you about the usual duration of the procedure. The time taken for the test varies and depends on the number of pictures (images) that your doctor requires. Normally taking the pictures (the scan) begins 45 minutes to 1 hour after your injection and takes 30 minutes to 1 hour to complete.

If you have been administered more Fludeoxyglucose Erigal than you should:

An overdose is almost impossible because you will only receive a single dose of Fludeoxyglucose Erigal precisely controlled by the specialist supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

In particular, the specialist in charge of the procedure may recommend that you drink a lot in order to help remove Fludeoxyglucose Erigal from your body. Fludeoxyglucose Erigal is removed from your body in urine.

Should you have any further questions on the use of Fludeoxyglucose Erigal, please ask your doctor or specialist.

4. Possible side effects

Like all medicines Fludeoxyglucose Erigal can cause side effects, although not everybody gets them.

Very few side effects have been reported with Fludeoxyglucose Erigal because the amount of radioactive drug that is injected is small. There is a very low risk of cancer and hereditary problems. Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

Possible side effects include itching, and a feeling of hotness or a swelling where the injection is given.

If any side effects get serious, or if you notice any side effects not listed on this leaflet, please tell your doctor or specialist.

5. How to store Fludeoxyglucose Erigal

Like all medicines, Fludeoxyglucose Erigal must be kept out of the reach and sight of children. Because Fludeoxyglucose Erigal is radioactive, it must always be handled and prepared in a special facility, such as a hospital Nuclear Medicine Department, which is licensed to receive, prepare and store this special type of medicine. The medicine must only be given to you by someone who is qualified to handle radioactive medicines. Do not store above 30°C. Do not use Fludeoxyglucose Erigal after the expiry date which is stated on the label. The medicine must be used within 12 hours of being made. After it is opened (by putting a needle through the top of the stopper and removing some of the radioactive liquid) the medicine can be used for up to 4 hours.

The container (a small glass bottle) must always be kept in an outer container that has a specific thickness to provide radioactive protection. Any medicine remaining after your injection will be disposed of by the hospital in accordance with the rules for handling this type of medicine.

6. Further information

What Fludeoxyglucose Erigal contains

The active substance is fludeoxyglucose (18F). 1 ml solution for injection contains 110-10,000 MBq fludeoxyglucose (18F) at the date and time of calibration. The other ingredients are: Water for Injections, Sodium Chloride and Sodium Dihydrogen Phosphate Dihydrate.

What Fludeoxyglucose Erigal looks like and contents of the pack

The medicine, Fludeoxyglucose Erigal, is a clear, colourless liquid that is provided in a small glass bottle with a rubber stopper and a cap. Because the medicine contains a small amount of radioactivity, it will be made especially for you and will be provided for you by your doctor just before it is injected into your vein. The amount that will be injected will vary depending on the diagnostic test that your doctor has asked for. The activity per vial ranges from 110 MBq to 50,000 MBq at the date and time of calibration.

Marketing Authorisation Holder and Manufacturer:

The MA Holder:

Erigal Ltd, Keele University Science Park, Keele, Staffordshire, UK.

Tel: 0044 1782 667680. Email: info@erigal.co.uk

Manufacturing sites:

Keele University Science Park, Keele, Staffordshire, UK.

Tel: 0044 1782 667680. Email: info@erigal.co.uk

Royal Preston Hospital, Fulwood, Preston, Lancashire, UK.

Tel: 0044 1772 772460. E-mail: info@erigal.co.uk

The Royal Marsden Hospital, Sutton, Surrey, UK.

Tel: 0044 208 661 6840. E-mail: info@erigal.co.uk

This leaflet was revised in September 2013

*Fludeoxyglucose (¹⁸F) Injection, Erigal is called Fludeoxyglucose Erigal throughout this leaflet.

Is this leaflet hard to see or read?

Phone 0044 1782 667680 for help
