



PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT
ERtracER Solution for Injection
Fludeoxyglucose (^{18}F)

Read all of this leaflet carefully before you are 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 ERtracER is and what it is used for.
2. What you need to know before ERtracER is administered.
3. How ERtracER is used.
4. Possible side effects.
5. How ERtracER is stored.
6. Contents of the pack and other information.

1. What ERtracER is and what it is used for.

This medicine is a radiopharmaceutical product for diagnostic use only. The active substance contained in ERtracER is fludeoxyglucose (^{18}F) and is designed for the capture of diagnostic images of some parts of your body.

Once a small amount of ERtracER has been injected, medical images that are obtained with a special camera will enable the doctor to capture images and see where your illness is or how it is progressing.

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 ERtracER 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 ERtracER 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. What you need to know before ERtracER is used

ERtracER must not be used

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

Warnings and Precautions

Talk to your doctor or the specialist in Nuclear Medicine before being administered ERtracER:

- if you are a diabetic and your diabetes is currently not controlled.
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 ERtracER with food and drink.
- if you have an infection or an inflammatory disease
- if you are affected by kidney problems

Inform your doctor or the specialist in Nuclear Medicine in the following cases:

- if you are pregnant or believe you may be pregnant
- if you are breast-feeding

Before administration of ERtracER 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 non-essential physical activity
- be fasting for at least 4 hours

Children and adolescents

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

Other medicines and ERtracER

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 (glycaemia), such as medicines that have an effect on inflammation (corticosteroids), medicines against convulsions (valproate, carbamazepine, phenytoin, phenobarbital), medicines affecting the nervous system (adrenaline, noradrenaline, dopamine),
- glucose,
- insulin,
- medicines used to increase the production of blood cells

ERtracER with food and drink

You should be fasting for at least 4 hours before the administration of the product. You should drink plenty of water and avoid drinking liquids containing sugar.

Your doctor or the specialist in nuclear medicine will measure your blood sugar before administering the product; indeed a high blood glucose concentration (hyperglycaemia) can make the doctor's interpretation more difficult.

Pregnancy and breast-feeding

You must inform the nuclear medicine doctor before the administration of ERtracER 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 product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding:

You must stop breast-feeding for about 12 hours after the injection and the maternal milk pumped must be discarded. Resuming breast-feeding should be in agreement with the doctor or specialist in nuclear medicine 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 doctor or the specialist in nuclear medicine for advice before you are administered this product.

Driving and using machines

It is considered unlikely that ERtracER will affect your ability to drive or to use machines.

ERtracER contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

ERtracER contains ethanol

This medicine contains up to 78 mg of alcohol (ethanol) in each 10 ml which is equivalent to 7.8 mg/ml (0.78% w/v). The amount in 1 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

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

3. How will ERtracER be used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. This product will only be used in special controlled areas. 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 ERtracER 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 ERtracER and conduct of the procedure

ERtracER 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. ERtracER 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 ERtracER, 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 have been given more ERtracER than you should

An overdose is unlikely because you will only receive a single dose of ERtracER 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 doctor or specialist in Nuclear Medicine in charge of the procedure may recommend that you drink abundantly in order to facilitate the elimination of ERtracER from your body (indeed the principle way of elimination of this product is renal, in the urine).

If you have any further questions on the use of ERtracER, please ask the 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.

Side effects with unknown frequency (cannot be estimated from the available data): **allergic reactions including serious allergic reactions like shock and cardiac arrest which may be life-threatening have been reported, with symptoms such as:**

- Difficulty breathing
- Shortness of breath
- Low blood pressure
- Skin rash (including rash erythematous, rash pruritic, rash maculo-papular)
- Hives, itching, dermatitis
- Redness of the skin (erythema)
- Swelling at various locations, swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. (angioedema), localised fluid accumulation (oedema)
- Eye irritation, eye disorders
- Cough
- Nausea and vomiting

Allergic reactions symptoms can start at different times for different people - either as an acute (immediate) reaction, appearing within minutes to a few hours, or as a delayed reaction, which can take up to 10 days to develop. Most commonly, symptoms appear within about 3 hours. In most cases, symptoms show up within 24 hours.. Allergic reactions can range from mild (such as rash, itching) requiring supportive treatments to serious allergic reactions which may require emergency support (hospitalization).

Prior to administration, your doctor should ask about your allergy history, medical histories, and current medications. Re-exposure to the drug can incur a risk of a recurrent reaction.

This radiopharmaceutical product will deliver a 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.

Reporting of Side Effects

If you get any side effects talk to your doctor or the specialist in Nuclear Medicine. This includes any possible side effects not listed on this leaflet. You can also report side effects directly in the Republic of Ireland via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

or in the United Kingdom directly via the Yellow Card Scheme Website at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Play App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How ERtracER is stored

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

The following information is intended for the specialist only:

This product must not be used after the expiry date which is stated on the label. This product must not be used if there are any visible signs of deterioration (it should be a clear colourless solution).

Use within four hours of withdrawing the first dose.

6. Contents of the pack and further information

What ERtracER contains

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

What ERtracER looks like and contents of the pack

The medicine, ERtracER, is a clear, colourless liquid that is provided in a small glass vial with a rubber stopper and a cap.

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 and manufacturer:

Curium Pharma Ireland Ltd, Blackrock Clinic, Blackrock, Dublin, Ireland.

Tel: 00353 1-206-4266. E-mail: info.ie@curiumpharma.com

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Phone 00 353 1 206 4266 for help