

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

### **Ceretec 500 micrograms kit for radiopharmaceutical preparation**

Exametazime

(called Ceretec in this leaflet)

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

#### **1. What Ceretec is and what it is used for**

Ceretec is a radiopharmaceutical product for diagnostic use only. It is used only to help identify illness.

Ceretec is given before a scan and helps a special camera see inside a part of your body.

- It contains an active ingredient called 'exametazime'. This is mixed with another ingredient called technetium' before it is used.
- Once injected it can be seen from outside your body by a special camera used in the scan.
- The scan can help your doctor see how much blood is flowing through the brain. This may be important to know after a stroke, if you have fits or epilepsy, Alzheimer's disease or a similar type of dementia. It may also be used in people who have migraine (headaches) or a brain tumour.
- The scan can help your doctor investigate fever when the reason for the fever is not known.
- The scan can also help your doctor investigate sites of infection, such as in your abdomen (the area around your stomach).
- Some other people are given this medicine to see swelling (inflammation) in the bowel.

Your nuclear medicine doctor will explain which part of your body will be scanned. The use of Ceretec does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit of this procedure with the radiopharmaceutical outweighs the risk of being exposed to these small amounts of radiation. Ask your nuclear medicine doctor if you have any questions.

## 2. What you need to know before Ceretec is used

### **Ceretec must not be used:**

- If you are allergic (hypersensitive) to the active ingredient or any other ingredients of this medicine (listed in Section 6).

### **Warnings and precautions**

Talk to your nuclear medicine doctor before using Ceretec:

- if the person who will be given this medicine is a child.
- if you are pregnant or think you may be pregnant.
- if you are breast-feeding.
- if you are on a low sodium diet.

### **Children and adolescents**

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

### **Other medicines and Ceretec**

Tell your nuclear medicine doctor who will supervise the procedure if you are taking, have recently taken or might take any other medicines, since they may affect the way Ceretec works.

No medicines have been reported that affect the way Ceretec works. But it is still best to tell your doctor or nurse if you are taking any other medicines.

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

You must tell your nuclear medicine doctor before you are given Ceretec 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 give this medicine during pregnancy if a benefit is expected which would outweigh the risk.

#### If you are breast-feeding

Do not breast-feed if you are given Ceretec. This is because small amounts of ‘radioactivity’ may pass into the mother’s milk. If you are breast-feeding, your nuclear medicine doctor may wait until you have finished breast-feeding before using Ceretec. If it is not possible to wait your nuclear medicine doctor may ask you to:

- stop breast-feeding for 12 hours, and
- use formula feed for your child, and
- express (remove) breast milk and throw away the milk.

Your nuclear medicine doctor will let you know when you can start breast-feeding again.

### **Driving and using machines**

It is considered unlikely that Ceretec will affect your ability to drive or to use machines. Ask your nuclear medicine doctor if you can drive or use machines after you have been given Ceretec.

### **Important information about some of the ingredients of Ceretec**

Ceretec contains sodium 1.77 mg per vial. This may need to be considered for people on a low sodium diet.

### 3. How Ceretec is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Ceretec will only be handled and given to you by professionals who are trained and qualified to use it safely.

#### Administration of Ceretec and conduct of the procedure

##### Dose

The nuclear medicine doctor supervising the procedure will decide on the amount of Ceretec to be used in your case. The doctor will choose the smallest amount necessary to get the desired information.

The amount to be administered usually recommended for an adult ranges from 555-1110 MBq for brain scintigraphy and 185 - 370 MBq for *in vivo* localisation of technetium-99m-labelled leucocytes. Megabecquerel (MBq) is the unit used to express radioactivity.

In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Samples that will be required before you have Ceretec

- A sample of your blood may be taken.

One injection is sufficient to carry out the scan that your doctor needs.

If a sample of your blood has been taken it will be mixed with a solution (containing Ceretec and the ingredient called 'technetium') which will then be given to you as an injection.

- Ceretec will always be used in a hospital or clinic
- Ceretec will be given to you by a specially trained and qualified person

They will provide you with the necessary information on the procedure.

##### Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

#### After administration of Ceretec you should:

- urinate frequently in order to eliminate the product from your body

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

#### If you are given more Ceretec than you should

An overdose is unlikely because you will only receive a single dose of Ceretec precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you would receive the appropriate treatment.

If you have any further questions on the use of this medicine, 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.

#### Allergic reactions

Tell your doctor straight away if you have an allergic reaction when you are in hospital or a clinic having the scan. The signs may include:

- skin rash or itching or flushing
- swelling of the face
- difficulty in breathing.

In more serious cases reactions may include:

- passing out (unconsciousness), feeling dizzy or lightheaded.

If any of the side effects above happen after you leave the hospital or clinic, you should go or be taken straight to the casualty department of your nearest hospital.

**Other side effects include (frequency not known)**

- itchy lumpy rash
- headache
- feeling dizzy
- flushing
- feeling sick (nausea)
- being sick (vomiting)
- general feeling of being unwell, weak or tired
- unusual feelings of numbness, tingling, prickling burning or creeping on skin.

This radiopharmaceutical will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

**Reporting of side effects**

If you notice any side effects, or if you notice any side effects not listed in this leaflet, please tell your Nuclear medicine doctor who supervises the procedure.

You can also report side effects directly to:

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How Ceretec is stored**

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

Hospital staff will ensure that the product is stored and disposed of correctly and not used after the expiry date stated on the label.

The following information is intended for healthcare or medical professionals only:

- Keep this medicine out of the sight and reach of children.
- Ceretec must not be used after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

- Ceretec must not be used if it is noticed that there are visible signs of discolouration or particulate matter.
- Before reconstitution: Store below 25°C. Do not freeze.
- Store the reconstituted product below 25°C. Do not freeze or refrigerate.
- The labelled product must be injected within 30 minutes of reconstitution.

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

### **What Ceretec contains**

- The active ingredient is exametazime. Each vial of Ceretec contains 500 micrograms of exametazime.
- The other ingredients are stannous chloride dihydrate and sodium chloride.

### **What Ceretec looks like and contents of the pack**

Ceretec is a white powder.

Ceretec is supplied as a kit for radiopharmaceutical preparation. The kit contains two or five vials. Not all pack sizes may be marketed.

Each vial contains 500 micrograms of exametazime.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

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### **Marketing Authorisation**

Ireland: PA 0735/013/001

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