

CERETEC™

For preparation of Technetium [^{99m}Tc] Exametazime Injection

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about CERETEC. It does not contain all the available information, nor does it take the place of talking to your doctor or treatment provider.

All medicines and diagnostic preparations have risks and benefits. Your doctor has weighed the risks of you being treated with CERETEC against the expected benefits.

If you have any concerns about being given this preparation, ask your doctor, or treatment provider.

Keep this leaflet.

You may need to read it again.

What CERETEC is used for

CERETEC is used in the preparation of a radiopharmaceutical which is a medicinal product containing a small amount of radioactivity.

Such radiopharmaceuticals are given in small amounts to find or rule out a disease. The radiation your body receives is very low and is considered safe. After the radioactive liquid is given to you, it is taken up by the organs of interest or just passes through your body. The radiation is taken up by a special camera and pictures are prepared. These pictures allow the nuclear medicine doctor to detect any problems.

In particular, CERETEC is used to produce images of the brain of patients who have fits or seizures. They occur when the brain's electrical currents become disordered from time to time in some people. This disease is called epilepsy. There is a number of different types of epilepsy. CERETEC is used particularly for the imaging of patients with epilepsy which originates in the parts of the brain just centre and slightly behind the ears.

CERETEC is used to help find or rule out a diagnosis only. It is not used to treat or cure epilepsy.

Your doctor may have prescribed CERETEC for another reason.

CERETEC is not recommended normally for use in children because studies have not been performed on the use of CERETEC in children. Nevertheless, your doctor may have decided to still use it and will have weighed up the risks and benefits.

Ask your doctor if you have any questions about why CERETEC has been prescribed for you.

Before you are given CERETEC

When you must not be given it

You must not be given CERETEC if you are allergic to it, or:

- any of the ingredients listed at the end of this leaflet or,
- have had a previous allergic reaction in a diagnostic

procedure with the same or similar preparation.

Before you are given CERETEC

Your doctor must know about all of the following before you are given CERETEC. Tell your doctor if you:

1. have allergies to:

- any other medicines, particularly those containing technetium or other imaging agents
- any other substances, such as foods, preservatives (substances to maintain food quality or freshness) or dyes (colourants)
- any of the ingredients of CERETEC listed at the end of this leaflet or to technetium (as CERETEC will be made up in a solution of Technetium and sodium chloride for injection).

2. are pregnant or intend to become pregnant in the near future.

CERETEC is to be avoided during pregnancy as adequate testing has not been performed. Your doctor may decide that the benefit may outweigh the risk.

Radiopharmaceuticals are not usually given to pregnant women to avoid exposing the foetus to radiation. However, some radiopharmaceuticals may be used for diagnostic tests in pregnant women, so it is important to inform your doctor if you are pregnant.

3. are breastfeeding.

Components of CERETEC may be excreted in the breast milk. Therefore, you should stop

breastfeeding and substitute formula feeds for at least 24 hours after you are given CERETEC or longer if your doctor tells you to.

4. **have, or have had any other medical conditions.**
5. **you plan to have surgery.**

If you have not told your doctor about any of the above, tell them before you are given CERETEC.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or treatment provider has more information on medicines to be careful with or to avoid when you are given CERETEC.

If you have not told your doctor about any of the above, tell them before you are given any CERETEC.

How CERETEC is given

Your doctor may have special instructions for you to follow to get ready for your procedure.

CERETEC is given as an injection into a vein. CERETEC must only be given by a doctor or nuclear medicine technologist.

Your doctor is qualified in nuclear medicine and will decide what dose of CERETEC you will receive, depending on your condition and other factors, such as your weight. In any case, the amount of radioactivity in the injection will not be big.

CERETEC is usually given as a single dose and within minutes after it is given diagnostic images will be taken.

If you have any questions about taking CERETEC or about the

diagnostic procedure, ask your doctor.

After being given CERETEC

CERETEC breaks down quickly after it is given and is virtually removed from the body after about 48 hours.

After completion of the examination, however, the doctor may ask you to go to the toilet to reduce the radiation dose to your bladder and the surrounding organs. You may also be asked to drink water to help with this process.

If you have any questions or concerns, be sure to discuss these with your doctor.

Side Effects

The following side effects have been reported after use of CERETEC:

- rash
- symptoms of allergy/sensitivity
- red skin
- swelling of the face
- fever
- brief increase in blood pressure

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of side effects. You may not experience any of them.

Overdose

The dose of CERETEC you will receive will be calculated by a qualified nuclear medicine doctor and given to you in a highly specialised setting. Therefore the possibility of overdose is minimal.

Storage

CERETEC will be stored by the hospital or clinic.

The hospital or clinic will make sure that CERETEC is not used if the expiry date (EXP) printed on the pack has passed.

Further information

This is not all the information that is available on CERETEC. If you have any more questions or are not sure about anything, ask your doctor or nuclear medicine technologist.

Product description

Ingredients

Each vial contains:

active ingredient -
exametazime 0.5mg

other ingredients -
sodium chloride
stannous chloride dihydrate
nitrogen gas in the headspace

Australian Registration Number:
AUST R 10018

Sponsor

CERETEC is made in England and supplied in Australia by:

GE Healthcare Australia Pty Ltd
ABN 32 001 408 402
241 O'Riordan St
Mascot NSW 2020

Tel 1300 887 764
Fax 1300 434 232

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