4.4 Special warnings and precautions for use

4.4.1 Overdose

In case of overdosage, the patient's condition should be carefully monitored. The initial symptoms include dizziness, vomiting, and ataxia. The patient should be kept in a recumbent position, oxygen therapy should be administered if necessary, and gastric lavage may be performed. Dialysis may be considered as a last resort.

4.4.2 Preclinical safety

The toxicological profile of the medicinal product has been evaluated in preclinical studies. The toxicity data are consistent with the clinical experience in humans. The medicinal product is generally well tolerated. However, in rare cases, allergic reactions or anaphylactic shock may occur, which should be managed promptly.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

The medicinal product is believed to work by binding to its receptor, leading to the desired therapeutic effect. The pharmacodynamic effect is thought to be mediated by a specific receptor on the target cell. The exact mechanism of action is not fully understood, but it is thought to involve a series of complex biochemical events.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of the medicinal product have been extensively studied. The drug is rapidly absorbed from the site of administration and distributed throughout the body. The drug is eliminated primarily through the kidneys, with a small fraction excreted in the bile.

5.3 List of excipients

The excipients used in this medicinal product are sodium chloride, sodium edetate, stannous chloride, tartaric acid, and ascorbic acid. The excipients are chosen to ensure the stability and efficacy of the medicinal product.

5.4 Special precautions for storage

The medicinal product should be stored at controlled room temperature (15-30°C) in a dry place, protected from light. The vials should be kept in their original packaging until use. After opening, the vials should be used immediately.

5.5 Nature and content of container

The medicinal product is supplied in vials for injection. Each vial contains 10 mg of EC and 10 mg of sodium edetate.

6. PHARMACEUTICAL FORM

6.1 Compendial requirements

The compendial requirements for the medicinal product are contained in the relevant pharmacopoeial monograph. The drug is manufactured in compliance with current Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).

6.2 Shelf life

The medicinal product is stable for 2 years if stored at ambient temperature and protected from light. After opening, the vials should be used immediately.

6.3 Special precautions for disposal and handling

The medicinal product is a radioactive medicinal product and should be handled with care. Special precautions should be taken to reduce the risk of radiation exposure. The medicinal product should be disposed of according to national regulations for radioactive waste.

7. INTERACTIVE INFORMATION

7.1 Medicinal products interaction

The medicinal product is not expected to interact with other medicinal products.

7.2 Laboratory tests

Routine laboratory tests should be performed before and after treatment with the medicinal product. These tests should include a complete blood count, renal and liver function tests, and a measurement of the dosage of the active ingredient.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy is not anticipated to result in adverse effects to the fetus. However, pregnant women should be advised of the potential risks associated with the use of this medicinal product.

8.2 Lactation

Lactation is not anticipated to result in adverse effects to the infant. However, breastfeeding women should be advised of the potential risks associated with the use of this medicinal product.

9. DERMATOLOGICAL USE

Dermatological use is not anticipated for this medicinal product.

10. OVERDOSAGE

In case of overdosage, the patient's condition should be carefully monitored. The initial symptoms include dizziness, vomiting, and ataxia. The patient should be kept in a recumbent position, oxygen therapy should be administered if necessary, and gastric lavage may be performed. Dialysis may be considered as a last resort.

11. SPECIAL MEASURES IN Case OF ACCIDENT OR OVERDOSAGE

The medicinal product is a radioactive medicinal product and should be handled with care. Special precautions should be taken to reduce the risk of radiation exposure. The medicinal product should be disposed of according to national regulations for radioactive waste.

12. DESCRIPTION

Tc-EC is a radioactive medicinal product that is administered to humans. The product is a pharmaceutical preparation containing 99mTc-EC in a vial for injection. The vials are manufactured in compliance with current Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).

13. ADVERSE REACTIONS

Adverse reactions are not expected with the use of this medicinal product. However, if an adverse reaction occurs, it should be reported to the appropriate regulatory authority.

14. CONTRAINDICATIONS

Contraindications to the use of this medicinal product are rare. However, patients with known allergies to the excipients should be advised of the potential risks associated with the use of this medicinal product.
Make sure you carry out the doctor's instructions both before and after the examination in order to avoid radioactive exposure of other people and the radioactive isotope is excreted in the urine, faeces, sweat and other secretions temporarily contaminating the environment this way. If you have any further questions on the use of this medicine, ask your doctor.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription. If you take ACE inhibitor medicines, tell to the doctor. No other interactions with other medicines are known.

Using EC kit with food and drink
You can take EC kit with any food or drink.

Pregnancy and breast-feeding
It is important to tell your doctor if there is any possibility that you are pregnant or breast-feeding.

In these cases your doctor will consider the necessity of the radioisotope diagnostic examination is up to the doctor. The decision will be made in accordance with strict regulations.

If you are breast-feeding and you will be examined with this product, you should stop breast-feeding for the period recommended by your doctor. During this time the radioisotope will be eliminated from your body.

Driving and using machines
Radioactive Tc-EC has no influence on the ability to drive and use machines. In these cases your doctor will consider the necessity of the radioisotope diagnostic examination is up to the doctor. The decision will be made in accordance with strict regulations.

How to storage EC kit
EC kit should be stored in refrigerator at 2 – 8 °C. Radioactive Tc-EC is to be stored below 25°C, considering the regulations for radiation safety.

EC kit contains:
- The active substance is 2.0 mg ethylene-L,L-dicystein (EC) in vial A.
- Other ingredients are:
  - vial-A: disodium hydrogenophosphate dihydrate, mannitol, sodium chloride.
  - vial-B: stannous chloride dihydrate, tartaric acid, ascorbic acid.
  - vial-C: potassium hydrogenophosphate, acetic acid.

How EC kit and Tc-EC injection look like and what is the contents of each?
EC kit contains radioactive isotope. For handling, shipping and storage of this product the rules and regulations referring to the radioactive materials should be observed.

The labelling procedure to obtain EC kit is described below.

There are strict rules and regulations for storage, handling, use and disposal of radioactive materials. Therefore, Tc-EC can only be used in hospitals or instutes, where radioactive material is permitted only in departments of nuclear medicine.

11. DOSIMETRY
Tc-EC injection is colourless or yellow solution which is prepared in the hospital isotope laboratories by using EC kit and Tc-EC-pertechnetate.

EC kit consists of vial-A, vial-B and vial-C. The injection vials containing the Tc-EC solution are sterile, freeze-dried product are closed with rubber stopper and tear-off kimbap (aluminium and plastic). One package of EC kit contains 4 vial-A, 4 vial-B and 4 vial-C.

The content of vial-A is homogeneous, white powder, while that of vial-B and vial-C can be pale yellow or yellow.

Marketing Authorisation Holder and Manufacturer
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12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
The amount of radioactivity in the body from EC kit depends on the quantity of the radiochemical impurities does not exceed 10%.

Control of the drug product
Radiochemical purity of Tc-EC is tested by using thin layer chromatography.

The radioactive isotope is excreted in the urine, faeces, sweat and other secretions temporarily contaminating the environment this way. If you have any further questions on the use of this medicine, ask your doctor.

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

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

Comply with the instructions given by your doctor.