Package leaflet: information for the patient
Edicis 2 mg kit for radiopharmaceutical preparation
Ethylenedicysteine

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 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. See section 4.

What is in this leaflet:

1. What Edicis is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Edicis is used for the preparation of a radioactive solution for injection of technetium (^{99m}Tc)-ethylenedicysteine. Technetium (^{99m}Tc) is a radioactive element allowing the visualisation of specific organs in your body by using special camera.
When binding ethylenedicysteine, technetium (^{99m}Tc) reaches kidneys via the bloodflow and is excreted in urine.

After injection of this product into one of your veins, your doctor will obtain images (known as a scan) of the kidneys and urinary tract. These images will give him information on the function of your kidneys and urinary tract..

The use of Edicis does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before Edicis is used

Edicis must not be used
if you are **allergic** to ethylenedicysteine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with Edicis:
Inform the specialist in Nuclear Medicine in the following cases :
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding
- if you had a scintigraphy with technetium in the last two days

Before administration of Edicis 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.

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

Other medicines and Edicis
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with the interpretation of the images. For example :
- diuretics (drug to increase urinary output),
- contrast media (drug administered before X ray examination).
- probenecid (drug used in the treatment of gout)

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of Edicis 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
Milk will be expressed before the injection and stored to be used later. Breast-feeding should be **interrupted for 24 hours** and the expressed milk during this period should be discarded.
Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
It is considered unlikely that Edicis will affect your ability to drive or to use machines.

Edicis contains less than 1 mmol of sodium (23 mg) per vial, i.e. essentially 'sodium- free'.
Edicis contains less than 1 mmol of potassium (39 mg) per vial, i.e. essentially potassium free'.

3. How Edicis is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Edicis 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 Edicis 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 90 MBq to 120 MBq (megabecquerel, the unit used to express radioactivity).

Administration of Edicis and conduct of the procedure
Edicis is administered by injection into a vein in your arm. One injection is sufficient to conduct the test.

In order to increase your diuresis an additional medication called furosemide can be administered.

Duration of the procedure
The duration of the examination depends on the type of investigation, it lasts about approximately 45 minutes.
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Edicis, you should:
- **avoid any close contact** with young children and pregnant women for the 24 hours following the injection.
- **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 have been given more Edicis than you should
An overdose is unlikely because you will only receive a single dose of Edicis precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will be asked to drink lots of water and urinate frequently.

Should you have any further question on the use of Edicis, 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.

No adverse effects have been reported to date.

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

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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

5. How Edicis 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.

The following information is intended for the specialist only.
Edicis must not be used after the expiry date which is stated on the labels after EXP.

6. Contents of the pack and other information

What Edicis contains
The active substance is: ethylenedicysteine.
One vial of Edicis contains 2 mg of ethylenedicysteine.

The other ingredients are:

Edicis:
- Disodium phosphate dihydrate (E339)
- Mannitol (E421)
- Ascorbic acid (E300)
- Disodium edetate dihydrate

Reducing agent:
- Stannous chloride dihydrate (E512)
- Tartaric acid (E334)
- Ascorbic acid (E300)

Buffer:
- Potassium dihydrogen phosphate (E340)
- Ascorbic acid (E300)

What Edicis looks like and contents of the pack
You will not have to get or to manipulate this medicine, what follows is only for your information.

Pack size:
Kit of 4 Edicis, 4 reducing agent and 4 buffer vials.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
CIS bio international
RN 306 – SACLAY
B.P.32
F-91192 GIF-SUR-YVETTE CEDEX

Manufacturer
INSTITUTE OF ISOTOPES Co., Ltd
Konkoly Thege Miklós út 29-33. ,
H-1121Budapest

This medicinal product is authorised in the Member States of the EEA under the name Edicis in : Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Norway, The Netherlands, Portugal, Spain, Sweden, United Kingdom:

This leaflet was last revised in 08/2013.

Detailed information on this medicine is available on the web site of the Irish Medecines Board (IMB).

The following information is intended for medical or healthcare professionals only:
The complete SmPC of Edicis is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.