

## Package leaflet: Information for the patient

### RENOCIS 1 mg kit for radiopharmaceutical preparation

#### Succimer

**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 RENOCIS is and what it is used for**
- 2. What you need to know before Renocis is used**
- 3. How Renocis is used**
- 4. Possible side effects**
- 5. How RENOCIS is stored**
- 6. Contents of the pack and other information**

#### **1. WHAT RENOCIS IS AND WHAT IT IS USED FOR**

This medicine is a radiopharmaceutical product for diagnostic use only.

The active substance of RENOCIS is succimer. **Renocis** is used in combination with a radioactive solution of technetium ( $^{99m}\text{Tc}$ ) in order to form a solution of technetium ( $^{99m}\text{Tc}$ ) succimer for injection.

When injected, technetium ( $^{99m}\text{Tc}$ ) succimer temporarily collects in your kidneys. Because of its radioactivity, it can be detected outside the body using a special camera, and pictures, known as scans, can be taken. These scans give valuable information about the structure and/or the functioning of your kidneys in the case of:

- renal infarction,
- atypical double kidney, small kidney, horseshoe kidney,
- unusual localisation of kidneys,
- absence of renal function in multicystic kidneys.

The use of Renocis 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 Renocis is used

### **RENOCIS must not be used:**

- if you are **allergic** to succimer or any of the other ingredients of RENOCIS (listed in section 6).

### **Warnings and precautions**

Take special care with RENOCIS

- If you **suffer from allergy**, since indeed some cases of allergic type reactions have been reported with this kind of examination.
- if you are **pregnant** or believe you may be pregnant.
- if you are **breast-feeding**
- if you have a kidney disease.

Please talk to your nuclear medicine doctor if any of the above applies to you. Renocis may not be suitable for you. Your nuclear medicine doctor will advise you.

### **Before administration of Renocis 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.

### **Other medicines and Renocis**

**Tell your nuclear medicine doctor** if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, since they may interfere with the interpretation of the images.

Your nuclear medicine doctor / doctor may recommend that you stop the following medicines before the procedure with Renocis:

- **Ammonium chloride** (used in the management of recurrent urinary tract infections),
- **Sodium bicarbonate** (drug that reduces the acidity of blood and / or urine)
- **Mannitol** (used to reduce intracerebral pressure)
- certain medicines for high blood pressure (the so-called ACE inhibitors such as captopril),
- cancer medicine such as methotrexate, cyclophosphamide, vincristine.

### **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 Renocis** 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**

It is recommended to avoid examination using technetium ( $^{99m}\text{Tc}$ ) during pregnancy because it may involve a risk to the foetus. 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**

**Tell your nuclear medicine doctor** if you are breast-feeding as he/she may delay the examination until breast-feeding is completed or ask you to stop breast-feeding for a short while until the radioactivity is no longer in your body.

Please ask your nuclear medicine doctor when you can resume breast-feeding. Usually it can be resumed 4 hours after injection.

**Driving and using machines**

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

**Renocis contains** less than 1 mmol of sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

**3. How RENOCIS is used**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Renocis 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 technetium ( $^{99m}\text{Tc}$ ) succimer 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 **30 to 120 MBq** (MBq: megabecquerel, the unit used to express radioactivity).

**Use in children and adolescents**

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

**Administration of Renocis and conduct of the procedure**

**Renocis** is administered by injection into a vein of your arm.

Only one injection is sufficient to conduct the test that your doctor needs.

**Duration of the procedure**

Your nuclear medicine doctor will inform you about the usual duration of the procedure. The scans can be taken from 1 to 3 hours after injection. Occasionally further scans may be required up to 24 hours after injection.

**After administration of Renocis**, you will be asked to drink as much as possible and 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 RENOCIS than you should**

An overdose is unlikely because you will only receive a single dose of Renocis, precisely controlled by the nuclear medicine doctor supervising the procedure.

However, in the case of an overdose, you will receive the appropriate treatment.

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

Cases of allergic reactions have been reported with unknown frequency from the data available.

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:

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 RENOCIS 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.

The kit should be stored in a refrigerator (2°C – 8°C).

The product should not be stored above 25°C after radiolabelling.

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

##### **What RENOCIS contains**

- The active substance is succimer (or dimercaptosuccinic acid).
- The other ingredients are: stannous chloride dihydrate (E 512), inositol, ascorbic acid (E300), sodium hydroxide (E524) under nitrogen atmosphere (E 941).

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

Renocis is a kit for radiopharmaceutical intended to be used by healthcare professionals only. You will not have to get this medicine or handle the packaging or the vial.

**Packsize:** kit of 5 multidose vials.

**Marketing Authorisation Holder and Manufacturer**

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RN 306 - Saclay  
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F-91192 Gif-sur-Yvette Cedex  
France

**The leaflet was last approved in xx/xxxx.**

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

The complete Summary of Product Characteristics (SmPC) of Renocis 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.