PACKAGE LEAFLET

Package leaflet: Information for the patient

Octreoscan

Kit for radiopharmaceutical preparation of ^{111}In-Pentetreotide 111 MBq/ mL

Read all of this leaflet carefully before you will be administered this medicine.
- 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 Octreoscan is and what it is used for

This medicine is a radiopharmaceutical product for **diagnostic use** only.

Octreoscan is used through a scan to locate specific cells in the stomach, bowel and pancreas such as:
- **abnormal tissue or**
- **tumours**

This medicine is a powder for solution for injection and a radioactive substance. These must not be used separately. When mixed together by qualified people and administered into the body it collects in specific cells.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the body. This gives the doctor valuable information about the structure and function of a specific part of the body.

The use of Octreoscan 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 Octreoscan is administered

Octreoscan must not be used
if you are allergic (hypersensitive) to pentetreotide or any of the other ingredients of Octreoscan (listed in section 6).

Warnings and precautions
Take special care with Octreoscan
- if you have reduced kidney function,
  your doctor will only administer Octreoscan in this case if it is absolutely necessary
- if you are **pregnant** or believe you may be pregnant
- if you are **breast-feeding**

Before Octreoscan administration you should:
- Drink at least 2 litres, such as water, and urinate as much as possible before and for 2 to 3 days after treatment. This will prevent active substance gathering in the kidneys and bladder.
- Your doctor may additionally prescribe a laxative for you.

Children and adolescents
Please speak to your Nuclear medicine doctor if you are under 18 years old. Octreoscan should only be administered to a child when alternative radiopharmaceuticals are not available or they do not yield a satisfactory performance in the clinical setting of the child.

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

The following medicines can **influence** or **be influenced by Octreoscan**:
- **Octreotide**, a medicine to treat the symptoms of certain tumours. Your doctor mayl temporarily stop octreotide. If octreotide discontinuation is considered, this should be done over a three day period to prevent side effects.
- **Insulin**
  Using Octreoscan in patients who use high insulin doses, severe lowering of blood sugar may occur.

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 Octreoscan 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 Octreoscan during **pregnancy if a benefit is expected, which would outweigh the risks**.

If you are **breast-feeding**
Tell your doctor if you are breast-feeding. If the administration is considered necessary, breast-feeding does not have to be discontinued. However, close contact with infants should be restricted during the first 36 hours after administration.

Please ask your Nuclear medicine doctor before taking any medicine.

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

3. How Octreoscan is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Octreoscan 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 Octreoscan to be used in your case. It will be the smallest quantity necessary to get the desired information.
The **quantity to be administered usually** and recommended for an **adult** ranges from

- 110 to 220 MBq

(Mega Becquerel, the unit used to express radioactivity).

Use in children and adolescents
The doctor will only administer Octreoscan to this age group if it is absolutely necessary. Octreoscan should only be administered to a child when alternative radiopharmaceuticals are not available or they do not yield a satisfactory performance in the clinical setting of the child.

Administration of Octreoscan and conduct of the procedure
Octreoscan is injected into a **vein**.
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.
Normally scans are made within a day or two after the injection. This depends on the information that is needed from the scans.
The scans are sometimes repeated within several days following the examination, to clearly understand the results.

After administration of Octreoscan, you should:
- Avoid any close contact with young children and pregnant women for the first 36 hours following the injection.
- Drink at least 2 litres, such as water and urinate frequently for 2 to 3 days after treatment in order to eliminate the product from your body.
- Your doctor will inform you if you need to take any special precautions after using this medicine. Contact your doctor if you have any questions.

If you have been given more Octreoscan than you should
An overdose is unlikely because you will only receive a single dose of Octreoscan precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive appropriate treatment.
Drinking as much as possible, such as water, will help remove the radioactive substance more quickly.

Should you have any further questions on the use of Octreoscan, ask your nuclear medicine doctor who supervises the procedure

4. Possible side effects

Like all medicines, Octreoscan can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:
uncommon, occurs in 1 to 10 per 1,000 users

- allergic reactions may occur with symptoms such as:
  - a warm flush
  - redness of the skin
  - itching
  - nausea or
  - difficulty breathing

  Healthcare staff will treat these reactions, if they occur.

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 doctor or nurse. 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; E-mail: medsafety@hpra.ie.* By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Octreoscan 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 information is intended for the specialist only.

Octreoscan will not be used after the expiry date which is stated on the label.

Octreoscan will not be used if it is noticed that the integrity of the tin can is broken and/or if one of the vials shows a damage.

6. Contents of the pack and further information

What Octreoscan contains
Octreoscan consists of one pack containing two vials (A and B). Vial A contains 1.1 mL solution, vial B contains powder for solution for injection.

The active substances are:
Vial A: Each vial contains 122 MBq ^{111}In as Indium chloride in 1.1 mL (111 MBq/mL) at the activityreference time.
Vial B: 10 microgram Pentetreotide.

Mixed solution (A plus B): ^{111}In-Pentetreotide 111 MBq/mL at the activity reference time.

The other ingredients are:
Vial A: hydrochloric acid, water for injection, ferric chloride hexahydrate.
Vial B: sodium citrate dihydrate, citric acid monohydrate, inositol, gentisic acid.

What Octreoscan looks like and contents of the pack

Octreoscan Kit for radiopharmaceutical preparation of ^{111}In-Pentetreotide, 122 MBq/1.1 mL at ART is supplied as a closed, folded tin containing two vials and a Sterican Luer Lock.

Vial A is a glass vial shielded with lead, containing a clear and colourless solution.
Vial B is a glass vial with grey butylrubber stopper and an aluminium crimp cap with orange flip off. It contains a white lyophilised powder.

The vials cannot be used separately.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Curium Netherlands B.V.,
Westerduinweg 3
1755 LE Petten, The Netherlands

PA690/1/1

Manufacturer
Curium Netherlands B.V.,
Westerduinweg 3
1755 LE Petten, The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium, Germany, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Sweden, United Kingdom: Octreoscan

This leaflet was last approved in 05/2019