

OctreoScan®

radiopharmaceutical precursor / powder for solution for injection

Active substances: ¹¹¹I as Indium chloride / Pentetreotide**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What OctreoScan is and what it is used for
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1. What OctreoScan is and what it is used for

This medicine is for diagnostic use only.

OctreoScan is used through a scan to locate specific cells in the stomach, bowel and pancreas such as:

- **abnormal tissues** 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 also 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. Before you use OctreoScan

Do not use OctreoScan

if you are

- allergic (hypersensitive) to pentetreotide or any of the other ingredients

Take special care with OctreoScan

Inform your doctor if you have

- reduced kidney function
Your doctor will only administer OctreoScan in this case if it is absolutely necessary.

This medicine does involve treatment with radioactivity. Your doctor will only give you this medicine if the benefit outweighs the risk.

OctreoScan is given by specialists, who will take responsibility for any necessary precautions.

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.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following **medicines** can **influence or be influenced by OctreoScan**:

- **octreotide**, a medicine to treat tumours, certain blood build-ups, swelling in the skin, and prevent pancreas problems after an operation
Your doctor will temporarily change your octreotide dose where possible. If octreotide discontinuation is considered, this should be done over a three day period to prevent side effects.
- **insulin**
Using simultaneously with high insulin doses can cause high blood sugar reductions. Blood sugar levels should therefore be measured.

Pregnancy and breast-feeding

- **Pregnancy**
Tell your doctor if you are pregnant or think you could be. Your doctor will **only** administer OctreoScan during **pregnancy if it is absolutely necessary**, as it could harm the unborn child.
- **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 and should be restricted during the first 36 hours after administration.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

OctreoScan is unlikely to impair the ability to drive and operate machinery.

3. How to use OctreoScan

OctreoScan will always be used in a hospital or similar setting. It will only be administered to you by qualified people trained to safe handle radioactive material.

Your doctor will decide the OctreoScan amount to be used. The lowest dose possible will be used to produce adequate X-ray images

The usual dose is:

Approximate doses for **adults** and the elderly are:

- 110-220 MBq injected into a vein
MBq is the unit used to measure radioactivity, and defines the activity of a quantity of radioactive material.

Children under 18 years

Lower doses are used for children according to their body weight. 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.

Method of use

One injection is usually sufficient. Scans are made 24 hours after the injection. The examination takes 30 to 90 minutes, depending on the number of scans.

The procedure is sometimes repeated on the first and second day following the examination, to clearly understand the results.

Drink at least 2 litres and urinate as much as possible before and 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.

If you take more OctreoScan than you should

It is unlikely that overdose will occur as this medicine is given under control by a doctor. However, if this happens you will receive appropriate treatment from your doctor.

Drinking as much as possible will help remove the radioactive substance more quickly.

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

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

Hospital 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 the national reporting system listed in [Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OctreoScan

Do not use OctreoScan after the expiry date stated on the label.

Hospital staff will ensure that the product and the ready to use solution are correctly stored: not above 25°C.

6. 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: 122 MBq ¹¹¹In as Indium chloride.
- Vial B: 10 µg Pentetretotide.

Mixed solution (A plus B): ¹¹¹In-Pentetretotide

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

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.

Marketing Authorisation Holder and Manufacturer

- **Marketing Authorisation Holder**
Mallinckrodt Medical B.V., Westerduinweg 3
1755 LE Petten, The Netherlands

PA690/1/1

- **Manufacturer**
Mallinckrodt Medical 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, Spain, Finland, France, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Sweden, United Kingdom: OctreoScan

This leaflet was last approved in November 2016.