Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about OctreoScan. It does not contain all of the available information about OctreoScan. It does not replace talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child receiving OctreoScan against the benefits he or she expects it will have.

If you have any concerns about receiving this medicine, ask your doctor.

Keep this leaflet. You may need to read it again.

What is OctreoScan

OctreoScan is a kit that consists of two components, OctreoScan 10 mL Reaction Vial containing pentetreotide and 10 mL vial of Indium (111In) Chloride Sterile Solution. These two components are combined on the day of intended use to form a single, sterile solution of the diagnostic agent Indium (111In) Pentetreotide.

What OctreoScan is used for

OctreoScan is used to diagnose tumours containing somatostatin receptors. These tumours are commonly found in the pituitary gland, pancreas and gastrointestinal system

Your doctor may have prescribed OctreoScan for another purpose. Ask your doctor if you have any questions about why OctreoScan has been prescribed for you. If you have any concerns, you should discuss these with your doctor.

This medicine is only available with a doctor's prescription.

Before you are given OctreoScan

Before you are given OctreoScan your doctor will explain to you the procedure you are about to undergo, and the radioactive medicine you will be given. You must discuss any concerns you have with your doctor.

OctreoScan is not recommended for patients less than 18 years of age. If your doctor believes it is necessary to give OctreoScan to a patient under 18, he or she will discuss the benefits and risks with you.

You must tell your doctor if you have allergies to:

- · any other medicines
- any other substances such as foods, preservatives or dyes

Tell your doctor if you are or plan to become pregnant.

Like most medicines OctreoScan is not recommended for use during pregnancy. If there is a need to consider OctreoScan during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Like most medicines OctreoScan is not recommended while you are breastfeeding. However if you are breastfeeding, formula feedings should be substituted for breastfeeding for 24 hours following the administration of OctreoScan. Breast milk

produced within that time should be discarded.

Tell your doctor if you have any other medical conditions especially if you suffer from diabetes or kidney failure.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from pharmacy, supermarket or health food shop.

How OctreoScan is given

How much is given

Your doctor will decide how much you will be given. This depends on your condition and other factors, such as weight.

How it is given

OctreoScan is given as an injection into a vein. OctreoScan should only be given by a doctor or a nurse.

When you are given OctreoScan

Things you must do

Make sure you are well hydrated prior to the administration of OctreoScan.

Things you must not do

Do not take any other medicines unless advised by your doctor.

Things to be careful of

OctreoScan should not affect your ability to drive or operate machinery.

OctreoScan is eliminated from the body through the kidneys.

Side Effects

Tell your doctor as soon as possible if you do not feel well after being given OctreoScan.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Tell your doctor if you experience any of the following and they worry you

- · Feel faint (Vasovagal reaction)
- Warmth and redness of skin (Flushing)
- Itching
- Hives

These side effects are usually mild. You may not experience any of them.

Product Description

What it looks like

OctreoScan is supplied as one pack containing two vials and a needle. The solution is prepared immediately prior to use and should be clear and colourless.

Ingredients

Active ingredients:

Vial A: Indium (¹¹¹In) chloride Vial B: lyophilised pentetreotide Final product: (¹¹¹In)-pentetreotide

Inactive Ingredients:

Vial A: Hydrochloric Acid, Water for Injection, Ferric Chloride Hexahydrate

Vial B: Sodium Citrate Dihydrate, Citric Acid Monohydrate, Inositol, Gentisic Acid

Sponsor

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