

# Indium In111 DTPA

## solution for injection

Indium (In111) pentetate and Pentetic acid

**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.

### In this leaflet:

1. What Indium In111 DTPA is and what it is used for
2. What do you need to know before Indium In111 DTPA is used
3. How is Indium In111 DTPA used
4. Possible side effects
5. How is Indium In111 DTPA stored
6. Contents of the pack and other information

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## 1. What Indium In111 DTPA is and what it is used for

This medicine is for diagnostic use only.

Indium In111 DTPA is used through a scan to examine:

- the brain and spinal cord
  - obstruction in the flow of cerebrospinal fluid, which is the fluid that envelops the brain and spinal cord
  - differentiation between normal pressure associated with hydrocephalus and other forms of hydrocephalus
- leakage of cerebrospinal fluid from the nose or ears.

This medicine contains a radioactive substance which when injected, collects in certain organs such as, the brain.

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 organ and body. This also gives the doctor valuable information about the structure and function of that organ.

The use of In111 DTPA 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.

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## 2. What do you need to know before Indium In111 DTPA is used

### Indium In111 DTPA must not be used

If you are allergic to Indium In111 DTPA or to any of the other ingredients of this medicine (listed in section 6.)

if you have

- a tendency to bleed
- increased pressure in your head, which is not associated with hydrocephalus

### Warning and precautions

Take special care with Indium In111 DTPA

This medicine does involve treatment with radioactivity. Your doctor will only give you this medicine if the benefit outweighs the risk. Indium In111 DTPA is given in one single dose 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 and Indium In111 DTPA

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines. There are no medicines known which influence or are influenced by Indium In111 DTPA.

### If you have been given more Indium In111 DTPA 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.

Should you have any further question on the use of Indium In111 DTPA, please ask the nuclear medicine doctor who supervises the procedure.

### **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 Indium DTPA 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.

- **Pregnancy**

The nuclear medicine doctor will **only** administer this product during **pregnancy if a benefit is expected which would outweigh the risk**, as it could harm the unborn child.

- **Breast-feeding**

Tell your doctor if you are breast-feeding as he may delay treatment until breast-feeding is finished. He may also ask you to stop breast-feeding for 2 days and discard this milk, until the radioactivity is no longer in your body.

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

### **Driving and using machines**

Indium In111 DTPA is unlikely to impair the ability to drive and operate machinery.

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## **3. How Indium In111 DTPA is used**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Indium In111 DTPA 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 Indium In111 DTPA to be used in your case. It will be the smallest quantity necessary to get the desired information.

### **The usual dose is:**

Approximate dose for **adults** is:

- 9 - 20 MBq injected into the skull or spine

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.

### **Administration of Indium In111 DTPA and conduct of the procedure**

One injection is usually sufficient.

### **Duration of the procedure**

The amount and duration of the scans usually depends on the type of procedure. Your Nuclear medicine doctor will inform you about the usual duration of the procedure.

### **After administration of Indium In111 DTPA, you should:**

#### **Drink and urinate as much as possible before and after treatment.**

This will prevent active substance gathering in the bladder. 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.

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## **4. Possible side effects**

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

In the majority of cases the side effects are mild.

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

**Frequency unknown**, from the data available

- headache and symptoms associated with irritation from linings which cover the brain or spinal cord  
Usually they improve within 48 hours.
- Meningitis
- Fever
- drooping of the eyelid or corner of the mouth
- ringing or buzzing in the ears

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: [hpra.ie](http://hpra.ie)

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

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## **5. How to store Indium In111 DTPA**

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.

- Keep this medicine out of the sight and reach of children
  - Do not use Indium In111 DTPA after the expiry date stated on the label.
  - Store below 25°C. If more than one dose is intended for use, the vial should be stored below 25°C after the first aliquot is taken.
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## **6. Contents of the pack and other information**

#### **What Indium In111 DTPA contains**

- The active substances are Indium (In111) pentetate and pentetatic acid.  
One millilitre of Indium In111 DTPA contains 37 MBq.
- The other ingredients are: sodium chloride, disodium phosphate dodecahydrate, calcium chloride dihydrate, sodium hydroxide, hydrochloric acid, water for injections.

#### **What Indium In111 DTPA looks like and contents of the pack**

Indium In111 DTPA is packaged in type 1 Ph.Eur glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap. It is supplied in one vial containing 0.5 or 1 mL.

#### **Marketing Authorisation Holder and Manufacturer**

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

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