

Technescan LyoMAA

Powder for Suspension for Injection
Kit for Radiopharmaceutical Preparation

Active substance: Macroaggregates of human serum albumin

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 nuclear medicine doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your nuclear medicine doctor.

In this leaflet:

1. What Technescan LyoMAA is and what it is used for?
2. Before you use Technescan LyoMAA
3. How to use Technescan LyoMAA?
4. Possible side effects
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1. What Technescan LyoMAA is and what it is used for?

This medicine is for **diagnostic use** only.

Technescan LyoMAA is a radiopharmaceutical product used when a diagnosis is made using radioisotopes.

When it is injected, it is temporarily taken up by certain organs. Since the product contains a small amount of radioactivity, it can be visualized from outside the body using special cameras, and an image can be taken (known as a scan). This scan shows the distribution of the radioactivity in the organ and how that organ is functioning.

Technescan LyoMAA can be used for **lung scans**. These scans provide information about the structure of the lungs and the blood flow through the lung tissue.

Technescan LyoMAA can also be used to show how the **blood flows through the veins**.

Your nuclear medicine doctor will tell you which specific investigation Technescan LyoMAA will be used for in your case.

2. Before you use Technescan LyoMAA

Do not use Technescan LyoMAA

if you

- are allergic (hypersensitive) to Technescan LyoMAA or any of the ingredients. (For a full list of ingredients please see section 6)
- if you have severe pulmonary hypertension (unusual high blood pressure in the arteries of the lungs)
In case of doubt, it is important to consult your nuclear medicine doctor.

Take special care with Technescan LyoMAA

Special care should be exercised when Technescan LyoMAA is administered to children and adolescents.

If you suffer or think you suffer from a heart condition or in particular from severe pulmonary hypertension (unusually high blood pressure in the arteries of the lungs), respiratory insufficiency or if you are aware of having a cardiac anomaly known as a cardiac right-to-left

shunt, please bring this to your nuclear medicine doctor's attention as such a condition may influence the investigation.

During the use of Technescan LyoMAA a small amount of radioactivity is administered. The associated risk is very small. Your nuclear medicine doctor will only carry out the investigation if he/she is convinced that the anticipated benefit of the investigation outweighs the risks.

Using other medicines

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

Other **medicines** may **influence the results** obtained using Technescan LyoMAA.

Specific examples include:

- a medicine to prevent **blood clotting (heparin)**
- **chemotherapeutic agents (busulfan, cyclophosphamide, bleomycin, methotrexate)**
- medicines used to treat **asthmatic conditions (bronchodilators)**,
- **heroin**
- some **antibiotics** (for example **nitrofurantoin**)
- some medicines used in the **prevention of headache** (for example **methysergide**)
- a medicine used as an **electrolyte replenisher (magnesium sulphate)**

Pregnancy and breast-feeding

• Pregnancy

It is important to tell your nuclear medicine doctor if you are pregnant or think you could be. The use of radiopharmaceuticals during pregnancy should be considered carefully. Your doctor will **only** administer Technescan LyoMAA during **pregnancy** if a benefit is expected which would outweigh the risks.

• Breast-feeding

If you are **breastfeeding**, please tell your nuclear medicine doctor, as he may advise you to **stop doing so** until the radioactivity has left your body. This takes **about 12 hours**. The expressed milk should be discarded.

Ask your nuclear medicine doctor for advice before taking any medicine.

Driving and using machines

Technescan LyoMAA has no or negligible influence on the ability to drive and use machines.

Important information about some of the ingredients of Technescan LyoMAA

Technescan LyoMAA contains less than 1 mmol sodium (23 mg) per vial, *i.e.* essentially "sodium-free".

3. How to use Technescan LyoMAA?

This radioactive medicinal product may only be used in accordance with your nuclear medicine doctor's instructions and under his supervision. Technescan LyoMAA must be reconstituted with a suitable sodium pertechnetate (^{99m}Tc) solution before it can be administered.

Your nuclear medicine doctor will decide what quantity of radioactive Technescan LyoMAA should be used. This will be the minimum amount required to obtain a clear scan with sufficient information. The amount can vary from **40 – 200 MBq** (Mega Becquerel, the unit to express radioactivity). **In children lower doses are used**, depending on their bodyweight.

- Technescan LyoMAA is administered by injection in a vein.
- Technescan LyoMAA is administered in one go.
- One injection is sufficient.
- The scans can be carried out any time after you have received the injection. Precisely when the scan will be carried out depends on the type of investigation.

Your nuclear medicine doctor may advise you to drink a lot to help the traces of radioactivity leave your body more quickly. This is normal when using diagnostic radiopharmaceuticals.

Do not hesitate to consult your nuclear medicine doctor if you are not sure.

If you have been administered more Technescan LyoMAA than you should

Since Technescan LyoMAA is administered under strictly controlled circumstances by a nuclear medicine doctor, it is unlikely that you will be given an overdose. Should this happen nonetheless, the nuclear medicine doctor will take appropriate measures.

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

4. Possible side effects

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

In very rare cases (less than 1 on 10.000 patients):

A very small number of patients have experienced hypersensitivity reactions, such as urticaria (hives), shivering fits, fever, sneezing, coughing, nausea, vomiting, difficulty breathing, oedema, reddening of the face and sweating as well as impairments of cardiac and circulatory functions in the form of changes in respiration, pulse, blood pressure and collapse.

Local allergic reactions in the form of redness, swelling, and itching at the injection site have been observed.

The appearance of these reactions may also not be immediate. In all these cases the reactions were short-lived and could be treated if necessary.

Very serious allergic reactions including shock with possible fatal outcome have been reported, although rarely.

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine 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 to store Technescan LyoMAA?

Keep out of the reach and sight of children.

Do not use Technescan LyoMAA after the expiry date stated on the label.

Hospital staff will ensure correct storage temperature as stated on the label:

- lyophilized powder should be stored at 2-8°C
- labelled product should be stored at 2-8°C Shelf life after reconstitution: 12 hours

Storage should be in accordance with national regulations for radioactive material.

Do not use Technescan LyoMAA if you notice cracks and/or a melted plug or any other indication that the integrity of the vacuum seal has been lost.

Following reconstitution, unused radiopharmaceutical and vial should be handled as radioactive waste and disposed of in accordance with local requirements.

6. Further information

What Technescan LyoMAA contains

- The active substance is: macroaggregates of human serum albumin, a natural protein from human blood
Each vial contains 2 mg macroaggregates of human serum albumin.

- The other ingredients are: sodium chloride, sodium acetate, stannous chloride dihydrate, hydrochloric acid and human serum albumin.

What Technescan LyoMAA looks like and contents of the pack

Technescan LyoMAA, lyophilisate for suspension for injection/kit for radiopharmaceutical preparation is a white freeze-dried powder and is packaged in 10 ml type I Ph. Eur. glass vials closed with a bromobutyl rubber stopper. It is supplied in one pack that contains 5 vials.

Marketing Authorisation Holder and Manufacturer

- **Marketing Authorisation Holder**
Curium Netherlands B.V., Westerduinweg 3
1755 LE Petten, The Netherlands
PA690/12/1

- **Manufacturer**
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