LeukoScan® sulesomab
Kit for the Preparation of Technetium -99m Labelled LeukoScan

What is in this leaflet

This leaflet answers some common questions about LeukoScan. It does not contain all the available information, nor does it take the place of you talking to your nuclear medicine specialist or physician.

All medicines and diagnostic agents have risks and benefits associated with their use. Your nuclear medicine specialist has weighed the risks of you being treated with LeukoScan against the benefits it is expected you will receive.

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

Name of your Medicine

LeukoScan is the trade name of your medicine. Sulesomab is the common name.

Product Description

Each 3-ml vial (glass container) contains 0.31mg of active substance, sulesomab, as a powder for solution for injection. The other ingredients are stannous chloride, sodium chloride, sodium potassium tartrate, sodium acetate and sucrose.

What LeukoScan is and what it is used for

An antibody is a natural substance made by the body which binds foreign substances to help remove them from your body. You produce many different kinds of antibodies. LeukoScan Sulesomab is a special kind of antibody which binds to the surface of certain kinds of blood cells called leukocytes. It is produced in mice and purified so that it can be used in humans. When it is combined to the radioactive technetium isotope and injected, it finds an abnormal accumulation of white blood cells and attaches to them. This helps your doctor make a diagnosis and evaluate the extent of your illness. The doctor does this by using a special imaging camera that reveals areas of radioactivity.

Therapeutic Group:

How LeukoScan Works.

LeukoScan is used to determine the present of infections in long bones. Shortly after mixing the LeukoScan with the radioactive technetium isotope, the doctor will inject it into your vein. One to eight hours later you will be placed on a special table and pictures will be taken with the standard nuclear cameras to see where the injections are located.
**Indications**

**When LeukoScan is used**

LeukoScan is an antibody fragment which is linked to a radioactive substance called technetium. LeukoScan is used in patients with suspected infection of the bone called osteomyelitis. The antibody is able to bind to the surface of the white blood cells which infiltrate the area of infection. When the radioactive antibody binds to the white blood cells, your doctor can determine where the injection is located by using a special imaging camera that reveals areas of radioactivity. The doctor can also determine how much disease there is. This will help the doctor determine whether there is an infection in the bone and what kind of treatment to use.

**Before you are given LeukoScan**

It is very important to tell the Nuclear Medicine Physician or Specialist if:

1. **You are or maybe pregnant**
   
   It is not known whether the injection is harmful to an unborn baby when administered to pregnant women. Tell your doctor if you are pregnant or are intending to become pregnant so that your doctor can decide if the potential benefit of administration of this injection exceeds any risk to you or your unborn child.

2. **You are breast-feeding**
   
   Radioactive technetium is excreted in human milk during lactation. If administration is considered necessary, breastfeeding should be interrupted and the expressed feeds discarded.

3. **You are allergic to any protein which is made from a mouse antibody**

4. **Do not use LeukoScan if you have an allergy to LeukoScan or any of the ingredients listed in the leaflet.**

5. **Do not use LeukoScan after the expiry date printed on the pack. If you use this medicine after the expiry date has passed, it may not work as well.**

6. **Do not use LeukoScan if the packaging is torn or shows sign of tampering.**

7. **Do not use LeukoScan if the powder or reconstituted solution is discoloured.**

**Precautions and Special Warnings**

**Things you should know before you are given LeukoScan**

It is possible to have a serious allergic reaction to LeukoScan, therefore your Nuclear Medicine Physician or Specialist should keep you under close observation for a short time after he has given you this drug.

If you have ever received LeukoScan or another product made from a mouse antibody, your Nuclear Medicine Physician or Specialist should take a sample of blood for testing to be sure that you have not developed antibodies which may cause an immune reaction if a further dose is given.
LeukoScan® sulesomab

Interactions with other Medications and other forms of Interaction

No interactions have been described to date.

Use of radiopharmaceutical agents

- Radiopharmaceutical agents can only be used by qualified personnel with appropriate government authorisation for the use and manipulation of radionuclides.

How to Use LeukoScan

Dosage: The Amount of Medicine Given

You will receive a single dose of 0.25 mg of LeukoScan. It will contain the radioactive technetium isotope in an amount called 740 – 1110 MBq.

Method and Route of Administration: How the injection is given to you

Your Nuclear Medicine Physician or Specialist will prepare the LeukoScan and the radioactive isotope technetium in a volume of 1.5 mL. 0.25 mg of LeukoScan will be labelled with the 740 – 1110 MBq of technetium. This material will then be injected into your vein. Nearly all of the radioactivity will be gone from the body in about 24 hours. Drink plenty of fluids before the examination and as often as possible afterwards for the next 4 to 6 hours. This will minimise the radiation dose to the bladder.

Frequency of Administration

How often will you be give LeukoScan

LeukoScan is prepared for a single injection. If your Nuclear Medicine Physician or Specialist decides to give it to you again after several months, your blood should be tested first to see if you have developed antibodies which may cause an immune reaction if a further dose is given.

Side Effects

Some side effects although not common, have been reported. These include a small increase in the number of certain white blood cells called eosinophils (but without any apparent symptoms) and rash. Rarely allergic reactions have occurred. If you experience either of these or any other unwanted effect after you are given this drug, tell your Nuclear Medicine Physician or Specialist.

Overdosage

The maximum amount of LeukoScan that can be administered has not been determined. Patients have been given four times the amount you will receive with no adverse reactions.

In the unlikely event of the administration of a radiation overdose with Leukoscan, the absorbed does to the patient may be reduced by increased oral or intravenous intake of fluids to promote excretion of the radiolabel.

Storage

Leukoscan is stored by the Hospital or Clinic. Your nuclear medicine technologist or specialist will check the expiry date before administering it.
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AUST R 82071

Supplier

LeukoScan in supplied in Australia by

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