DRAXIMAGE® MAA

Kit for the Preparation of Technetium [^{99m}Tc] Albumin Aggregated Injection

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about DRAXIMAGE® MAA. It does not contain all the available information, nor does it take the place of talking to your doctor or treatment provider.

All medicines and diagnostic preparations have risks and benefits. Your doctor has weighed the risks of you receiving DRAXIMAGE® MAA against the expected benefits.

If you have any concerns about being given DRAXIMAGE® MAA, ask your doctor or treatment provider.

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

What DRAXIMAGE® MAA is used for

DRAXIMAGE® MAA is for diagnostic use only.

It is used in the preparation of a radiopharmaceutical, which is a medicinal product containing a small amount of radioactivity.

Such radiopharmaceuticals are given in small amounts to find or rule out a disease. The radiation your body receives is very low and is considered safe. After the radioactive liquid is given to you, it is taken up by the organs of interest or just passes through your body. The radiation is captured by a special camera and pictures are prepared. These pictures allow the nuclear medicine doctor to detect any problems.

DRAXIMAGE® MAA can be used for lung scans. These scans provide information about the structure of the lungs and the blood flow through the lung tissue.

DRAXIMAGE® MAA can also be used to show how the blood flows through the veins.

Your doctor will tell you which specific investigation DRAXIMAGE® MAA will be used for in your case.

Before you are given DRAXIMAGE® MAA

When you must not be given DRAXIMAGE® MAA

Do not use DRAXIMAGE® MAA if you are allergic (hypersensitive) to macroaggregated human albumin or any of the ingredients of DRAXIMAGE® MAA listed at the end of this leaflet, or if you have severe pulmonary hypertension (unusually high blood pressure in the arteries of the lungs). The literature contains reports of deaths after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. In case of doubt, it is important to consult your doctor.

Before you are given DRAXIMAGE® MAA

Your doctor must know about all of the following before you are given DRAXIMAGE® MAA. Tell your doctor if you:

1. **Are pregnant:**
   The use of radiopharmaceuticals during pregnancy should be considered carefully. Your doctor will only administer this product during pregnancy if a benefit is expected which should outweigh the risks.
2. **Are breastfeeding:**
   Your doctor may advise you to interrupt breastfeeding after the procedure for a period of at least 12 hours and to discard expressed milk during that time. Breastfeeding may be resumed after the prescribed period.

Taking other medicines

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

Your doctor or treatment provider has more information on medicines to be careful with or to avoid when you are given DRAXIMAGE® MAA.

If you have not told your doctor about any of the above, tell them before you are given any DRAXIMAGE® MAA.

About blood products

This product contains albumin, a derivative of human blood. When medicines are made from human blood or plasma, measures are put in place to prevent infection transmission. Despite this, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

How DRAXIMAGE® MAA is given

Your doctor may have special instructions for you to follow to get ready for your procedure.

DRAXIMAGE® MAA is given as an injection into a vein.

DRAXIMAGE® MAA must only be given by a doctor or nuclear medicine technologist. Your doctor is qualified in nuclear medicine and will decide what dose of DRAXIMAGE® MAA you will receive, depending on your condition. The amount of radioactivity you will receive can vary from 37 to 148 MBq (Mega Becquerel, the unit used to express radioactivity).

DRAXIMAGE® MAA is usually given as a single dose and, within minutes after it is given, diagnostic images will be taken.

If you have any questions about taking DRAXIMAGE® MAA or about the diagnostic procedure, ask your doctor.

After being given DRAXIMAGE® MAA

Your 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. Your doctor will also tell you about any other steps you may need to take following the use of this product.

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

Side Effects

Like all medicines, DRAXIMAGE® MAA may cause side effects, although not everybody gets them. Most people have no side effects.

A very small number of patients have experienced allergic reactions such as urticaria (hives or red raised itchy bumps on the skin), nausea and reddening of the face. Local injection site reactions in the form of redness, swelling and itching have also been observed.

Other side effects may include fever, shivering, seizures, sweating, as well as impairments of cardiorespiratory and circulatory functions in the form of changes in respiration, pulse, low blood pressure and fainting.

Importantly, if any side effects gets serious or when in doubt, seek prompt medical attention. If treated immediately, reactions were short-lived.

If you notice side effects not listed in this leaflet, it is important that you speak to your doctor or pharmacist.

Overdose

The dose of DRAXIMAGE® MAA you will receive will be calculated by a qualified nuclear medicine doctor and given to you in a highly specialized setting. Therefore the possibility of overdose is minimal.

Storage

DRAXIMAGE® MAA will be stored by the hospital or clinic. The hospital or clinic will make sure that DRAXIMAGE® MAA is not used if the expiry date printed on the pack has passed.

Further information

This is not all information that is available on DRAXIMAGE® MAA. If you have any more questions or are not sure about anything, ask your doctor or nuclear medicine technologist.

Product description

What it looks like

DRAXIMAGE® MAA is a white powder. It comes in a 10 mL glass vial.

Ingredients

The active substance is a natural protein from human blood: macroaggregated human albumin.

Each reaction vial contains:

- 2.5 mg of albumin aggregated
- 5.0 mg of albumin human
- 0.1 mg of stannous chloride dehydrate
- 1.2 mg of sodium chloride

Australian Registration Number

AUST R 261212

Sponsor

DRAXIMAGE® MAA is manufactured by:

Jubilant DraxImage Inc.
16751 TransCanada Highway, Kirkland,
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DRAXIMAGE® MAA is distributed in Australia by:

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