DOTAREM® injection

gadoteric acid

Consumer Medicine Information

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS
Gadolinium-based contrast agents increase the risk for nephrogenic systemic fibrosis (NSF) in patients with:
- acute or chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73m^2), or
- acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period.

WHAT IS IN THIS LEAFLET

This leaflet provides only a summary of the information known about DOTAREM. It does not contain all the available information. It does not take the place of talking to your doctor or health care professional.

All diagnostic agents have risks and benefits. Your doctor has weighed the risks of you using DOTAREM against the benefits it is expected to have for you.

If you have any concerns about using this diagnostic agent, ask your doctor or radiologist.

If you have any questions, want to know more about DOTAREM or are unsure about anything, ask your specialist or radiologist.

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

Remember that this injection is only for you. Only a doctor can prescribe it for you.

WHAT DOTAREM IS USED FOR

DOTAREM contains gadoteric acid, which is made from gadolinium oxide (a magnetic agent) and DOTA, which binds with the gadolinium oxide to make a contrast agent to help diagnosis in MRI (magnetic resonance imaging).

This is injected into your veins just before a MRI examination.

MRI is a form of medical diagnostic imaging that forms pictures after detecting water molecules in normal and abnormal tissues. This is done using a complex system of magnets and radiowaves.

BEFORE YOU ARE GIVEN DOTAREM

When you must not be given it

You must not be given DOTAREM if you have:

- **ever had an allergic (hypersensitive) reaction to the active substance, gadoteric acid, or to the other ingredients in DOTAREM.** Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
- **any metallic foreign objects in your body such as a pacemaker or vascular clips.** Before the examination, remove all metallic objects that you wear. This is very important because metals could cause serious disorders, since MRI machines use very strong magnetic fields.

Before you are given it

Tell your doctor know if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- bronchial asthma
- very poor kidney function or severe kidney problems
- you have had or will soon have a liver transplant
- a low threshold for seizures
- any allergies (e.g. seafood allergy, hayfever, hives)
- Severe heart and circulatory disorders

There have been reports of a serious disease called nephrogenic systemic fibrosis (NSF) in kidney disease and liver transplant patients when they have used these types of products.

Tell your doctor if you are pregnant, breast feeding or if you are likely to become pregnant shortly.

Taking other medicines

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

Some medicines may interfere with DOTAREM. These include medicines used to treat hypertension.

HOW DOTAREM IS GIVEN

How much is given

The doctor will determine the lowest effective dose that you will receive and will supervise the injection. The usual dose for adults, children and infants is 0.2 mL/kg.

How it is given

DOTAREM will be given to you as a single intravenous injection. You will be monitored for any side effects for at least 30 minutes after the injection.

When opened, this product should be used once only and any residue discarded.

If you are given too much (overdose)

As you will be administered the injection under the supervision of your doctor in a hospital, it is highly unlikely that you will be given too much.

However, if you experience any side effects after being given DOTAREM Injection, tell your doctor or nurse immediately.
You may need urgent medical attention.

Also, immediately tell the doctor or medical staff or telephone the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice if you think a child or anyone else may have been given too much DOTAREM.
Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

AFTER HAVING DOTAREM

Things you must do

Follow carefully the directions given to you by your doctor and other medical staff.

Things to be careful of

Tell your doctor if you are going to have any laboratory tests.

SIDE EFFECTS

DOTAREM, like most other medicines and diagnostic agents can cause side effects in some people. These side effects can sometimes be serious but they are usually mild to moderate and short-lasting.

Most side effects occur during injection or during the first hour after the injection. Some side effects may appear several days after the injection of DOTAREM.

Tell your doctor as soon as possible if you do not feel well whilst receiving or after being given DOTAREM

The most common side effects during administration of DOTAREM include headache, dizziness, changes to taste, tingling sensation, sensation of warmth or cold and/or pain at the injection site, nausea, vomiting, hypertension, hypotension, abdominal pain and mild allergic reactions (usually affecting the skin such as rash and itchiness).

There is a small risk that you may have an allergic reaction to DOTAREM. Such reactions can be severe and result in shock (case of allergic reaction that could put your life in danger). The following symptoms may be the first signs of a shock. Inform your doctor, radiologist or health professional immediately if you feel any of them:

- **swelling of the face, mouth or throat which may cause you difficulties in swallowing or breathing**
- **swelling of hands or feet**
- **lightheadedness (hypotension)**
- **breathing difficulties**
- **whistling respiration**
- **coughing**
- **itching**
- **runny nose**
- **sneezing**
- **eye irritation**
- **hives**
- **skin rash**

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Some of these side effects could be the first signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

Allergic reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur, causing low blood

pressure, loss of consciousness or heart attack, increase in heart rate, difficulty breathing, and swelling of the face, lips or tongue leading to severe breathing difficulties and shock may occur.

Tell the doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Rarely, delayed reactions can occur.

There have been reports of nephrogenic systemic fibrosis (which causes hardening of the skin and may affect also soft tissue and internal organs), most of which were in patients who received DOTAREM together with other gadolinium-containing contrast agents. If, during the weeks following the MRI examination, you notice changes in the colour and/or thickness of your skin in any part of your body, inform the radiologist who performed the examination

AFTER USING IT

Storage

As this is being given to you by your doctor, it is extremely unlikely that you will be expected to look after the injection. However, in the case that you may have to transport it from the pharmacy to your doctor, it is important to store it in a safe place, away from light, where the temperature stay below 30°C. The pre-filled DOTAREM syringes should not be frozen.

Do not use DOTAREM if the packaging is torn or shows signs of tampering or after the expiry date printed on the label.

Keep all medicines in a safe place where children cannot reach them.
They may be dangerous to children.

PRODUCT DESCRIPTION

What it looks like

DOTAREM is a clear, colourless to yellow solution available in a glass vial or glass or plastic pre-filled syringe intended for intravenous injection.

DOTAREM contains gadoteric acid 279.32 mg/mL. It also contains the inactive ingredients meglumine and water for injections.

DOTAREM is registered in packs of 1 glass vial, with volume fill of 5 mL, 10 mL, 15 mL and 20 mL.

DOTAREM is registered in packs of 1 glass pre-filled syringe, with volume fill of 10 mL, 15 mL and 20 mL.

DOTAREM is registered in packs of 10 plastic pre-filled syringes, with volume fill of 10 mL, 15 mL and 20 mL.

The Australian Registration numbers are:

20 mL vial - AUST R 76923

15 mL vial - AUST R 76924

10 mL vial - AUST R76925

5 mL vial - AUST R 76926

20 mL PFS - AUST R 160800

15 mL PFS - AUST R 160799

10 mL PFS - AUST R 160798

SPONSOR

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