PACKAGE LEAFLET: INFORMATION FOR THE USER

DOTAREM 279.32 mg/ml
Solution for injection

Gadoteric acid

Read all of this leaflet carefully before you start using 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 doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dotarem is and what it is used for
2. What you need to know before you are given Dotarem
3. How you will be given Dotarem
4. Possible side effects
5. How to store Dotarem
6. Contents of the pack and other information

1. WHAT DOTAREM IS AND WHAT IT IS USED FOR

Dotarem is a diagnostic agent used in adults and children. It belongs to the group of contrast agents used for magnetic resonance imaging (MRI).

Dotarem is used to enhance the contrast of the images obtained during MRI examinations. This contrast enhancement improves the examination of some areas of the body.

This medicine is for diagnostic use only.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DOTAREM

You should NOT be given DOTAREM
- if you are allergic to the active substance or any of the other ingredients of this medicine(listed in section 6)
- if you are allergic to medicines containing gadolinium (like other contrast agents used for MRI).

Warnings and precautions
Inform your doctor or radiologist if the following applies to you:
- you have previously reacted to a contrast agent during an examination
- you have asthma
- you have a history of allergy (such as seafood allergy, urticaria, hay fever)
- you are being treated with a beta-blocker (medicine for heart and blood pressure disorders, such as metoprolol)
- your kidneys do not work properly
- you have recently had, or soon expect to have, a liver transplant
- you have a disease affecting your heart or your blood vessels
- you have had convulsions or you are being treated for epilepsy.

In all these cases, your doctor or radiologist will assess the benefit-to-risk ratio and decide whether you should be given Dotarem. If you are given Dotarem, your doctor or radiologist will take the precautions necessary and the administration of Dotarem will be carefully monitored.

Your doctor or radiologist may decide to take a blood test to check how well your kidneys are working before making the decision to use Dotarem, especially if you are 65 years of age or older.

Neonates and infants
As kidney function is immature in babies up to 4 weeks of age and infants up to 1 year of age, Dotarem will only be used in these patients after careful consideration by the doctor.

Remove all metallic objects that you wear before the examination. Inform your doctor or radiologist if you have:
- a pacemaker
- a vascular clip
- an infusion pump
- a nerve stimulator
- a cochlear implant (implant in the inner ear)
- any suspected metallic foreign bodies, particularly in the eye.

This is important as these can result in serious problems, as MRI devices use very strong magnetic fields.

Other medicines and Dotarem
Tell your doctor or radiologist if you are taking, have recently taken or might use any other medicines.
In particular, please inform your doctor, radiologist or pharmacist if you are taking or have recently taken medicines for heart and blood pressure disorders such as beta-blocking agents, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists.

Dotarem with food and drink
There are no known interactions between Dotarem and food and drink. However, please check with your doctor or pharmacist if it is required not to eat or drink before the examination.

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 doctor or radiologist for advice before taking this medicine.

Pregnancy
Dotarem should not be used during pregnancy unless strictly necessary.

Breast-feeding
Your doctor or radiologist will discuss whether you should continue breast-feeding or interrupt breast-feeding for a period of 24 hours after you receive Dotarem.

Driving and using machines
No data are available on the effects of Dotarem on the ability to drive. If you feel unwell after the examination, like nausea (feeling sick), you should not drive or use machines.

3. HOW YOU WILL BE GIVEN DOTAREM

Dotarem will be administered to you by intravenous injection.

During the examination, you will be under the supervision of a doctor or radiologist. A needle will be left in your vein; this will allow the doctor or radiologist to inject you with appropriate emergency drugs if necessary. If you experience an allergic reaction, the administration of Dotarem will be stopped.

Dotarem can be administered by hand or by the mean of an automatic injector. In neonates and infants, the product will only be administered by hand.

The procedure will be carried out in a hospital, clinic or private practice. The attending staff knows what precautions have to be taken for the examination. They are also aware of the possible complications that can occur.

Dosage
Your doctor or radiologist will determine the dose you will receive and supervise the injection.

Dosage in special patient groups
The use of Dotarem is not recommended in patients with severe kidney problems and patients who have recently had, or soon expect to have, a liver transplant. However if use is required you should only receive one dose of Dotarem during a scan and you should not receive a second injection for at least 7 days.

Neonates, infants, children and adolescents
As kidney function is immature in babies up to 4 weeks of age and infants up to 1 year of age, Dotarem will only be used in these patients after careful consideration by the doctor. Children should only receive one dose of Dotarem during a scan and should not receive a second injection for at least 7 days. Use for angiography is not recommended in children less than 18 years of age.

Elderly
It is not necessary to adjust your dose if you are 65 years of age or older but you may have a blood test to check how well your kidneys are working.

If too much Dotarem has been administered to you
It is highly unlikely that you will be given an overdose. You will be given Dotarem in a medical setting by a trained person. In the real case of overdose, Dotarem can be removed from the body by haemodialysis (blood cleaning).

Additional information regarding the use and handling by the medical or healthcare professional is given at the end of this leaflet.

If you have any further questions on the use of this medicine ask your doctor or radiologist.

4. POSSIBLE SIDE EFFECTS

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

After the administration, you will be kept under observation for at least half an hour. Most side effects occur immediately or sometimes delayed. Some effects can occur up to seven days after Dotarem injection.

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 immediately your doctor, radiologist or health professional if you feel any of them:
- swelling of the face, mouth ot 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.

Uncommon side effects (may affect up to 1 in 100 people)
- hypersensitivity
- headaches
- unusual taste in the mouth
- dizziness
- somnolence
- sensation of tinglings, warmth, cold and/or pain
- low or high blood pressure
- nausea (feeling sick)
- stomach pain
- rash
- feeling hot, feeling cold
- asthenia
- injection site discomfort, injection site reaction, injection site coldness, injection site swelling, diffusion of the product outside of blood vessels that can lead to inflammation (redness and local pain).

Rare side effects (may affect up to 1 in 1,000 people)
- anxiety, faintness (dizziness and feeling of imminent loss of consciousness)
- eyelid swelling
- palpitations
- sneezing
- vomiting (being sick)
- diarrhoea
- increased saliva secretion
- hives, itching, sweating
- chest pain, chills.

Very rare side effects (may affect up to 1 in 10,000 people)
- anaphylactic or anaphylactic-like reactions
- agitation
- coma, seizures, syncope (brief loss of consciousness), disorder of smell (perception of often unpleasant odours), tremor
- conjunctivitis, red eye, blurred vision, increased tear secretion
- cardiac arrest, accelerated or slow heartbeat, irregular heartbeat, vascular dilatation, pallor
- respiratory arrest, pulmonary oedema, breathing difficulties, wheezing, stuffy nose, cough, dry throat, throat constriction with feeling of suffocation, respiratory spasms, throat swelling
- eczema, redness of the skin, swelling of the lips and localised in the mouth
- muscle cramps, muscle weakness, back pain
- malaise, chest discomfort, fever, swelling of the face, diffusion of the product outside of blood vessels that can lead to tissue dying off at the injection site, inflammation of a vein
- decrease in oxygen level in blood.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or radiologist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For Ireland:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

For United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE DOTAREM

Keep this medicine out of the sight and reach of children..

The vials do not require any special storage conditions. The pre-filled syringe must not be frozen.

Do not use this medicine after the expiry date which is stated on the vial or the pre-filled syringe and on the carton, after the abbreviation “Exp”. The expiry date refers to the last day of that month.

It is unlikely that you will be asked to dispose of any left over Dotarem. If this happens ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dotarem contains

- The active substance is gadoteric acid. One ml of solution for injection contains 279.32 mg of gadoteric acid (as meglumine salt), equivalent to 0.5 mmol of gadoteric acid.
- The other ingredients are meglumine and water for injection.

What Dotarem looks like and contents of the pack

Dotarem is a clear, colourless to yellow solution for intravenous injection.
The Dotarem pack contains one glass vial of 5, 10, 15 or 20 ml or one glass pre-filled syringe of 10, 15 or 20 ml.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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93600 Aulnay-sous-Bois
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Guerbet Laboratories Ltd.,
Avon House,
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This medicinal product is authorised in the Member States of the EEA under the following name: Dotarem

This leaflet was last revised in November 2017.

The following information is intended for medical or healthcare professionals only:

Prior to administration of Dotarem, it is recommended that all patients are screened for renal dysfunction by obtaining laboratory tests.

There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR< 30ml/min /1.73 m^2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. As there is a possibility that NSF may occur with Dotarem, it should therefore only be used in patients with severe renal impairment and in patients in the perioperative liver transplantation period after careful risk/benefit assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI. If it is necessary to use Dotarem, the dose should not exceed 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, Dotarem injections should not be repeated unless the interval between injections is at least 7 days.

Due to immature renal function in neonates up to 4 weeks of age and in infants up to 1 year of age, Dotarem should only be used to this group of patients after careful consideration at a dose not exceeding 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, Dotarem injections should not be repeated unless the interval between injections is at least 7 days.

As the renal clearance of Dotarem may be impaired in the elderly, it is particularly important to screen patients aged 65 years and older for renal dysfunction.

Haemodialysis shortly after Dotarem administration may be useful at removing Dotarem from the body. There is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis.

Dotarem should not be used during pregnancy unless the clinical condition of the woman requires use of gadoteric acid.

Continuing or discontinuing breast feeding for a period of 24 hours after administration of Dotarem, should be at the discretion of the doctor and lactating mother.

The peel-off tracking label on the vials or syringes should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded. If electronic patient records are used, the name of the product, the batch number and the dose should be entered into the patient record.

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