PATIENT INFORMATION LEAFLET

Scheduling Status

S4

DOTAREM® Solution for Injection

DOTAREM® PREFILLED SYRINGES Solution for Injection

Gadoteric acid

Sugar free

Read all of this leaflet carefully before you are given Dotarem

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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 magnetic resonance imaging (MRI)).

Warnings and precautions

Tell your doctor or radiologist before being given Dotarem 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 (this includes complementary or traditional 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 Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or radiologist for advice before Dotarem is administered to you.

Pregnancy

Dotarem can cross the placenta. It is not known whether it affects the baby. Dotarem should not be used during pregnancy unless strictly necessary.

Breastfeeding

Your doctor or radiologist will discuss whether you should continue breastfeeding or interrupt breastfeeding 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 medicines if necessary. If you experience an allergic reaction, the administration of Dotarem will be stopped.

Dotarem can be administered by hand or by the means 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).

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

4. Possible side effects

Dotarem can have side effects.

Not all side effects reported for Dotarem are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being administered Dotarem, please consult your healthcare provider for advice.

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. Tell your doctor, radiologist or healthcare

provider immediately if you notice the following:

- 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.

Tell your doctor if you notice any of the following:

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any **side effects, talk to your doctor or X-ray specialist**.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on the SAHPRA website:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8.

Guerbet South Africa (Pty) Ltd: pharmacovigilance.za@guerbet.com

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

5. How to store Dotarem

Store all medicines out of reach of children.

Store at or below 30 ºC.

Prefilled syringes: Do not freeze.

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. Each 100 ml of solution contains 27,932 g of gadoteric acid equivalent to DOTA (20,246 g) and to gadolinium oxide (9,062 g)).

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.

Dotarem sterile solution for injection is available in clear glass vials containing 5 ml, 10 ml, 15 ml, 20 ml, 60 ml and 100 ml and Dotarem Prefilled Syringes in 10 ml, 15 ml and 20 ml plastic prefilled syringes.

Dotarem sterile solution for injection and Dotarem Prefilled Syringes are sold as single units or as 10 units per pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Dotarem: 31/28/0550

Dotarem Prefilled Syringes: 31/28/0551

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Guerbet South Africa (Pty) Ltd

E-mail: pharmacovigilance.za@guerbet.com