Package leaflet:Information for the user

Omniscan 0.5 mmol/ml solution for injection
Omniscan 0.5 mmol/ml solution for injection, pre-filled syringe

Gadodiamide

Read all of this leaflet carefully before you are given Omniscan 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.
- If you get any side effects, talk to you doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What OMNISCAN is and what it is used for

This medicine is for diagnostic use only.
Omniscan is a contrast medium which is used in Magnetic Resonance Imaging (MRI) examinations of the brain or spine, and for whole body examinations like the head and neck region, the thoracic cavity including the heart, extremities (arms and legs), organs in the abdominal cavity (prostate, urinary bladder, pancreas and liver), kidney, female breast, musculosceletal system and blood vessels.

Omniscan can help some medical conditions to be seen more clearly. This helps the doctor to find and examine these conditions more easily, and can improve the information needed to make a diagnosis.

2. What you need to know before you are given Omniscan

Do not use Omniscan
- if you are allergic (hypersensitive) to gadodiamide or any of the other ingredients of Omniscan (listed in section 6)

You should not be given Omniscan if you suffer from severe and/or acute kidney problems, or if you are a patient who is about to have or has recently had a liver transplant, as use of Omniscan in patients with these conditions has been associated with a disease called nephrogenic systemic fibrosis (NSF). NSF is a disease involving thickening of the skin and connective tissues. NSF may result in severe joint immobility, muscle weakness or may affect the normal working of internal organs which may potentially be life threatening. Omniscan should also not be given to newborn babies up to age of 4 weeks.

Warning and precautions
Talk to your doctor before using Omniscan
- if you have a heart pacemaker or any implants containing iron in your body
- if you have previously experienced a severe reaction after receiving contrast media
- if you have or have had any allergies (e.g. allergies to seafood, hay fever, nettle rash), asthma or other allergic respiratory disorders.

- if you suffer from heart diseases or disorders of the central nervous system (epilepsy or brain lesions).
- if you suffer from moderate kidney problems.

Tell your doctor if:
- your kidneys do not work properly
- you have recently had, or soon expect to have, a liver transplant

Before you receive Omniscan, you will need to have a blood test to check how well your kidneys are working.

Children and adolescents
Omniscan should not be used in newborn babies up to the age of 4 weeks. As kidney function is immature in infants up to 1 year of age, Omniscan will only be used in infants after careful consideration by the doctor.

O**ther medicines and Omniscan**
Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Tell your doctor if you are having blood samples taken on the same day and within 12-24 hours after Omniscan injection. Omniscan interferes with some of the methods commonly used for measuring content of electrolytes (e.g. iron and calcium) in blood.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

Pregnancy
You must tell your doctor if you think you are or might become pregnant as Omniscan should not be used during pregnancy unless strictly necessary.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding should be discontinued for at least 24 hours after you receive Omniscan.

Driving and using machines
Driving should be avoided since nausea may occur after the investigation.

Omniscan contains 0.62 mg/ml Sodium. This needs to be considered for people on a low sodium diet.

3. How to use Omniscan

Dosage and administration
Omniscan will be injected into one of your veins usually as a single injection before or during your MRI examination. Occasionally a second injection may be of additional diagnostic value.

The amount injected will depend upon your weight and what part of the body you are having examined. The usual dose is 0.2 ml/kg body weight or occasionally up to 0.6 ml/kg body weight. Even if you weigh more than 100 kg you will normally not receive more than 20 ml or for some conditions up to 60 ml.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Dosage in special patient groups

You should not be given Omniscan if you suffer from severe kidney problems and/or acute kidney injury or if you are a patient who is about to have or has recently had a liver transplant. Omniscan should also not be used in newborn babies up to the age of 4 weeks.

If you have moderate kidney problems, you should only receive one dose of Omniscan during a scan and you should not receive a second injection for at least 7 days.

As kidney function is immature in infants up to 1 year of age, infants should only receive one dose of Omniscan during a scan and should not receive a second injection for at least 7 days.

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

4. Possible side effects

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

The following rare symptoms may be serious. Contact your doctor immediately if you experience:

- Symptoms of angioedema, such as
  - swollen face, tongue or pharynx,
  - difficulty to swallow,
  - hives and difficulties to breath
- Symptoms of Nephrogenic systemic fibrosis (NSF) such as:
  - thickening of the skin
  - severe joint immobility
  - muscle weakness

This is a list of side effects which may occur during or after the examination:

Common (may affect up to 1 in 10 people):

- Transient discomfort in the form of a sensation or warmth
- Coolness or local pressure in connection with injection
- Transient sensation of pain at the injection site
- Headache
- Nausea.

Uncommon (may affect up to 1 in100 people):

- Allergy-like skin and mucous membrane reactions
- Hypersensitivity.
- Dizziness.
- Tingling sensations.
- A transient change in your sense of taste.
- Vomiting.
- Diarrhoea.
- Flushing.
- Itching.

Rare (may affect up to 1 of 1,000 people):

- A transient change in your sense of smell.
- Cramps.
- Drowsiness.
- Difficulty in breathing.
- Pain in the joints.
- Trembling.
- Anxiety.

- Visual disturbances.
- Chest pain.
- Acute renal failure.
- Coughing.
- Rash and hives.
- Swelling, including face swelling.
- Fever.
- Shivering.

Not known (frequency cannot be estimated from the available data)
- Anaphylactic/anaphylactoid reactions
- Rapid pulse.
- Sneezing.
- Irritation in the throat.
- Severe difficulty in breathing.
- Thickening of the skin.

Most of the allergic reactions occur within half an hour after injection. In rare cases side effects may occur after hours or days.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: [To be completed nationally]
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omniscan

Keep out of the sight and reach of children.
Do not use Omniscan after the expiry date which is stated on the label.

The peel-off tracking label on the vial/bottle and pre-filled syringe 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

Store the vial/bottle/polypropylene bottle and pre-filled syringe in the outer carton in order to protect from light.
Store the polypropylene bottles with twist-off top below 30°C.
Do not freeze.
Do not use Omniscan if you notice severe discoloration, the occurrence of particulate matter or a defective container

Chemical and physical in-use stability has been demonstrated for 8 hours at 25 °C. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

6. Contents of the pack and other information

What Omniscan contains

* The active substance is gadodiamide (287 mg of gadodiamide per ml, equivalent to 0.5 mmol/ml)
  1 ml contains 287 mg of gadodiamide, equivalent to 0.5 mmol.
  5 ml contains 1.44 g of gadodiamide, equivalent to 2.5 mmol.
  10 ml contains 2.87 g of gadodiamide, equivalent to 5.0 mmol.
  15 ml contains 4.31 g of gadodiamide, equivalent to 7.5 mmol.
  20 ml contains 5.74 g of gadodiamide, equivalent to 10.0 mmol.
  50 ml contains 14.35 g of gadodiamide, equivalent to 25.0 mmol.
  100 ml contains 28.70 g of gadodiamide, equivalent to 50.0 mmol.

* The other ingredients are caldiamide sodium and sodium hydroxide solution 3.8 % or hydrochloric acid 3.65 % (for pH adjustment) and water for injections.

What Omniscan looks like and contents of the pack

Omniscan is a solution for injection. The product is a clear, colourless to slightly yellow, aqueous solution.

Omniscan is supplied as:

5 ml, 10 ml, 15 ml, 20 ml and 100 ml glass vials/bottle with chlorobutyl rubber stoppers (latex free).
Pack sizes of 10.

10 ml, 15 ml and 20 ml polypropylene bottles, with twist-off top and luer-lock.
Pack sizes of 10.

50 ml and 100 ml polypropylene bottles, with chlorobutyl rubber stopper, plastic screw cap and tamper proof ring.
Pack sizes of 10.

10 ml, 15 ml and 20 ml pre-filled syringes, with bromo-butyl or styrene-butadiene rubber plungers that do not contain latex.
Pack sizes of 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

GE Healthcare AS
Nycoveien 1-2
P.O. Box 4220 Nydalen
NO-0401 OSLO, Norway

Manufacturer

GE Healthcare Ireland Limited
IDA Business Park
Carrigtohill
Co. Cork, Ireland

Or

GE Healthcare AS,
Nycoveien 1-2,
P.O.Box 4220 Nydalen,

NO-0401 Oslo,
Norway

This medicinal product is authorised in the Member States of the EEA under the following names:
Germany: Omniscan 0,5 mmol/ml Injektionslösung
Ireland: Omniscan 0.5 mmol/ml Solution for Injection
Norway: Omniscan 0.5 mmol/ml Injeksjonsvaeske
Sweden: Omniscan 0.5 mmol/ml Injektionsvätska

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

Each vial/bottle and pre-filled syringe of contrast medium is intended for single use. Any unused portions must be discarded.

The diameter of the pre-filled syringe is too large to allow for accurate measurements of small volumes. The syringe should not be used for volumes below 5 ml.

If this medicinal product is intended to be used with an automatic application system, its suitability for the intended use has to be demonstrated by the manufacturer of the medical device. Instructions for use of the medical device must be followed absolutely.

Prior to administration of Omniscan, all patients should be screened for renal dysfunction by obtaining laboratory tests.

There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of Omniscan and some other gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30 ml/min/1.73m^2) and/or acute kidney injury. Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. Therefore Omniscan must not be used in patients in the perioperative liver transplantation period.
Omniscan should also not be given to newborn babies up to the age of 4 weeks.

The risk for development of NSF in patients with moderate renal impairment (GFR 30–59 ml/min/1.73 m^2) is unknown, therefore, Omniscan should be only used after careful risk-benefit evaluation in patients with moderate renal impairment 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, Omniscan injections should not be repeated unless the interval between injections is at least 7 days.

Due to immature renal function in infants up to 1 year of age, Omniscan should only be used in these 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, Omniscan injections should not be repeated unless the interval between injections is at least 7 days. Omniscan should not be given to newborn babies up to age of 4 weeks.

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

Haemodialysis shortly after Omniscan administration may be useful at removing Omniscan 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.

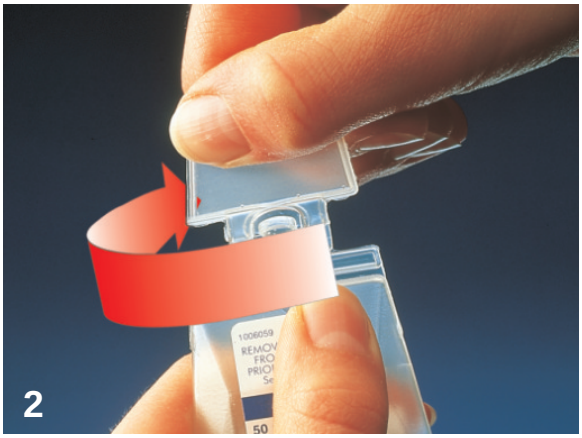
Omniscan should not be used during pregnancy unless the clinical condition of the woman requires use of gadodiamide.

Breast-feeding should be discontinued for at least 24 hours after the administration of Omniscan.

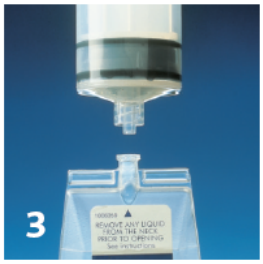
The peel-off tracking label on the vials/bottles and syringes should be stuck onto the patient record to enable accurate recording of the gadolinium contrast agent used. The dose used should also be recorded.

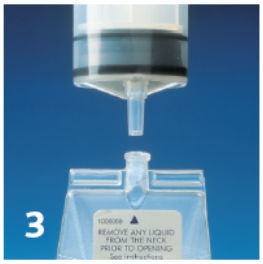
Instruction for use of the polypropylene bottle

1. Before opening, remove any liquid from the neck of the bottle.



2. *Twist* the top off with a *quick* movement.





3. Attach the syringe directly to the neck of the bottle.