Consumer Medicine Information

What is in this leaflet

This leaflet tells you about OMNISCAN™. The information in this leaflet applies only to OMNISCAN.

This leaflet answers some common questions about OMNISCAN. It does not contain all the available information about the product and is not intended to replace discussions you may wish to have with your doctor, radiologist or other health professional.

All medicines have risks and benefits. Your doctors have weighed the risks of you being given this medicine against the benefits they expect it will have for you.

Please read this leaflet before you are given OMNISCAN.

If you have any questions, are not sure about anything or if you have any concerns about being given this medicine - ask your doctor, radiographer or nurse.

Keep this leaflet, you may need to read it again.

What OMNISCAN is used for

OMNISCAN is one of a group of medicines known as ‹contrast media› which are used in Magnetic Resonance Imaging (MRI) examinations.

OMNISCAN is used in MRI examinations of the brain or spine, as well as other parts of the body. OMNISCAN makes it easier to detect and locate changes and to improve the diagnostic information your radiologist needs.

OMNISCAN is intended for use in hospitals and radiology clinics only.

OMNISCAN is for use in adults, children and babies over 4 weeks of age.

How OMNISCAN works

MRI uses the magnetic properties of molecules in the body to “see” organs and other structures in the body and how they may have changed as a result of any condition you may have. OMNISCAN can greatly improve the clarity of the images the radiologist looks at to enable better, and more accurate, diagnosis of your condition.

What is in OMNISCAN

The name of your medicine is OMNISCAN. It contains an active substance known as gadodiamide.

OMNISCAN is a sterile, aqueous solution for injection, and contains 287 mg of gadodiamide per mL (equivalent to 0.5 mmol per mL).

Other ingredients are small amounts of caldiamide sodium and sodium hydroxide or hydrochloric acid (for pH adjustment), and water for injections.

Before being given OMNISCAN

If the answer to any of the following questions is YES, tell the doctor BEFORE you are given OMNISCAN.

- Do you have an allergy or asthma?
- Are you pregnant, or think you might be pregnant?
- Have you ever had an allergic reaction to OMNISCAN, to any of its ingredients or to any other ‹contrast media›?
- Do you suffer from any kidney problems or have reduced kidney function or are you undergoing dialysis?
- Have you undergone liver transplantation or are you waiting to do so?
- Are you currently taking any other medications that you have been prescribed by your doctor or bought yourself from a pharmacy?

How you will be given OMNISCAN

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 your body you are having examined. The usual dose is 0.2 mL/kg. Occasionally, a second dose of 0.4 mL/kg may be of additional diagnostic value. If you weigh more than 100 kg, you will normally receive 20 mL or, occasionally, a second dose of 40 mL.

During, and after, your examination

Usually, OMNISCAN does not cause any problems. It can, however, sometimes cause unwanted effects in some people. The most frequent effect is mild discomfort in the form of a sensation of warmth, cold, pressure or pain in the area around where the injection is given.

Although there is a risk that you might get an unwanted effect, your doctor will have chosen this ‹contrast medium› by considering these risks and the benefits of the examination.

If you get any of the following during, or after, the examination:

- wheeziness, difficulty in breathing or tightness, pain in the chest or heart palpitations
- skin rash, lumps, itchy throat or spots
- a decrease in the amount of urine you pass, or a change in its colour

- you should tell the doctor straight away.

Other unwanted effects which are unusual, but which may occur during, or after, the examination include:

- a change in your sense of smell or taste
- dizziness
- throat irritation sneezing or coughing
- headache
- indigestion, nausea and/or vomiting, diarrhoea
- weakness or drowsiness
- cramps in arms, legs, other muscles or joint pain
- tingling sensations
- hearing or sight problems
- anxiety, trembling, convulsions, shivering
- fever
- facial swelling

These effects are usually mild and of short duration. If they become severe, or last more than a few days, tell your doctor.

In patients with severely reduced renal function receiving OMNISCAN, a disease called nephrogenic systemic fibrosis (NSF) has rarely been observed, days to weeks after the examination. NSF causes discolouration and thickening of the skin. NSF may be painful and may result in reduced joint mobility, muscle weakness or impairment of the function of internal organs which may potentially be life threatening.

If you experience any other unwanted effects, please tell your doctor.

If you are given too much OMNISCAN (overdose)

As OMNISCAN will be given to you by a qualified person familiar with the procedure, overdosage is very unlikely to occur. But, in the event this happens, qualified personnel are available and know what to do to handle such an occurrence.

Other important information

OMNISCAN can affect the results of blood sample tests taken on the same day as your examination.

Please tell your doctor if you give a blood sample on the same day as you were given OMNISCAN.

If you are breast feeding

It is not known whether OMNISCAN passes into the breast milk. Just to be sure, **do not give your baby any breast milk expressed in the first 24 hours after your examination.**

Product Description

OMNISCAN is available in the following presentations:

Glass Vials;

5 mL (AUST R 62200)*
10 mL (AUST R 46378)*
15 mL (AUST R 47379)*
20 mL (AUST R 47380)*

Polypropylene Ampoules;

10 mL (AUST R 60112)*
15 mL (AUST R 60114)*
20 mL (AUST R 60113)*
40 mL (AUST R 72351)*
50 mL (AUST R 72352)*

Prefilled Syringes

10 mL (AUST R 74070)*
15 mL (AUST R 74069)*
20 mL (AUST R 74071)*

Storing the medicine

- The expiry date is printed on the label. The product should not be used after this date.
- OMNISCAN, in glass vials, polypropylene ampoules and prefilled syringes, is stored below 30°C (do not freeze) and protected from light.
- The vial/ampoule/prefilled syringe is intended for one patient only. Any unused portions must be discarded.

Where to go for further information

Please ask your doctor, radiologist or nurse if you would like to know more, or have any questions about OMNISCAN.

Who supplies this medicine

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Some presentations may not currently be available in Australia.