



# Safety Information 002/17

**15 August 2017**

**Distributed to:**

- Chief Executives
- Directors of Clinical Governance
- Directors of Medical Services
- Heads of Radiology Departments
- Relevant clinicians
- Clinical Product Managers

**Expert Reference Group**

Content reviewed by:

- ACI – Radiology Network

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## Gadolinium-based contrast agents for MRI scans

**Purpose of gadolinium-based contrast agents**

Gadolinium-based contrast agents are injected into a patient's vein to enhance the quality of magnetic resonance imaging [MRI] scans of internal organs, blood vessels and tissues.

**Retention of gadolinium in the brain and other body regions**

Recent publications relating to the potential for small amounts of gadolinium to be retained in the brain, even in patients with normal renal function, following the use of gadolinium-based contrast agents during MRI scans have been reviewed.

No harmful effects of gadolinium retention in the brain have been identified at this time.

While much remains to be discovered about the mechanism, dynamics and long-term consequences of gadolinium retention, available evidence indicates the following:

1. Small amounts of gadolinium are retained in the brain (and other tissues, notably bone) after gadolinium-based contrast administration.
2. The extent, and possibly duration, of this retention varies with different contrast agents [and their chelating ligand]; in general, retention appears greater with ligands with a linear molecular structure.
3. The chemical form or forms (and hence likely residence time) of retained gadolinium in human tissues is not known in detail, and may also vary with the chelating ligand used.
4. At present, no adverse effect of gadolinium retention has been demonstrated.
5. It is prudent to restrict the use of gadolinium-based contrast agents to situations where such use is reasonably expected to provide additional useful diagnostic information. This particularly applies to the repeated use of such agents in serial examinations.
6. The dose of gadolinium-based contrast agents should be limited to the minimum necessary to acquire the relevant diagnostic information.
7. In the context of the recent findings, particular care should be taken with the use of gadolinium-based contrast agents in the following patient groups:
  - **those with renal impairment**
  - **paediatric patients**, for whom the consequences of long-term gadolinium retention are potentially of most concern
  - **obstetric patients**, where the extent and consequences of gadolinium retention in the placenta and/or foetus are not well understood.

Notably, 'routine' use of contrast in these patients, where there is not a specific indication (such as monitoring, or reasonable suspicion, of enhancing tumour) should be reviewed.

8. Practitioners may wish to review their choice of gadolinium chelate.
9. Judicious use of marketed gadolinium-based contrast agents remains appropriate.

**References**

RANZCR *Statement on Gadolinium Retention*, 28 July 2017 at <https://www.ranzcr.com/whats-on/news-media/171-ranzcr-statement-on-gadolinium-retention>

TGA *Gadolinium-based contrast agents for MRI scans, Safety advisory – potential retention in the brain but no known adverse effects*, 28 July 2017 at <https://www.tga.gov.au/alert/gadolinium-based-contrast-agents-mri-scans>

**Suggested actions by Local Health Districts/Networks**

1. Distribute this Safety Information to all relevant clinical staff and clinical product managers to ensure they are aware of the issues relating to the use of gadolinium-based agents for MRI scans.
2. Review the choice of gadolinium chelate used for MRI scans, and ensure MRI and use of contrast agents comply with NSW Health policies.



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## Gadolinium-based contrast agents for MRI scans

### Types of gadolinium-based contrast agents

Published studies have found that **linear** gadolinium-based contrast agents appear to result in greater gadolinium retention in the brain than macrocyclic gadolinium-based contrast agents.

The following table details the gadolinium-based contrast agents available in Australia.

Product name - Gadolinium chelate	Sponsor	Chelate structure	Comment
Multihance - gadobenate dimeglumine	Bracco Pty Ltd	Linear	Some albumin binding and biliary excretion
Gadovist - gadobutrol	Bayer Australia Ltd	Macrocyclic	
Omniscan - gadodiamide	GE Healthcare Australia Pty Ltd	Linear	
Magnevist - gadopentetate dimeglumine	Bayer Australia Ltd	Linear	
Dotarem - gadoteric acid	Apollo Imaging Solutions Pty Ltd	Macrocyclic	
Prohance - gadoteridol	Bracco Pty Ltd	Macrocyclic	
Optimark - gadoversetamide	Guerbet Australia Pty Ltd	Linear	
Primovist - disodium gadoxetate	Bayer Australia Ltd	Linear	50% biliary excretion

### Use of gadolinium-based contrast agents in the NSW public health system

1. Gadolinium-based contrast agents for MRI are used in the NSW public health system.
2. MRI and use of contrast agents in the NSW public health system are used in compliance with policies including [Clinical Procedure Safety PD2014\\_036](#) and [Medication Handling in NSW Public Health Facilities PD2013\\_043](#).
3. Appropriate patient consent protocols are required to be in place and correctly documented; refer to [Consent to Medical Treatment – Patient Information PD2005\\_406](#).
4. Many radiology units in NSW have developed checklists for in-house use to assist their staff members to avoid harm to their patients from this procedure. These checklists ensure that patients have had a recent renal function test.
5. The [Agency for Clinical Innovation Radiology Network](#) has been investigating a statewide form to support contrast use.