GADOVIST® 1.0

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I given GADOVIST 1.0?

GADOVIST 1.0 contains the active ingredient gadobutrol. GADOVIST 1.0 is a contrast agent used during a magnetic resonance imaging (MRI) examination.

For more information, see Section 1. Why am I given GADOVIST 1.0? in the full CMI.

2. What should I know before I am given GADOVIST 1.0?

Do not use if you have ever had an allergic reaction to GADOVIST 1.0 or any of the ingredients listed at the end of the CMI.

Talk to your doctor, radiographer or nurse if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given GADOVIST 1.0? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GADOVIST 1.0 and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given GADOVIST 1.0?

GADOVIST 1.0 is injected into your vein by a doctor, radiographer or nurse immediately before or during your MRI examination.
It is recommended that you do not eat for 2 hours before you are given GADOVIST 1.0.

More instructions can be found in Section 4. How am I given GADOVIST 1.0? in the full CMI.

5. What should I know while receiving GADOVIST 1.0?

Things you should do	Tell your doctor, radiographer or nurse if you have: • experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock • have very poor kidney function or severe kidney problems • had a liver transplant, impaired liver function or liver cirrhosis • have severe heart and circulatory disorders • have low threshold for seizures.
Looking after your medicine	The MRI unit will store GADOVIST 1.0 as required by the manufacturer.

For more information, see Section 5. What should I know while receiving GADOVIST 1.0? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Serious side effects can include severe allergic reactions, breathing or lung issues, nephrogenic systemic fibrosis (NSF) and heart attack. Common side effects can include headache, nausea and dizziness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Gadolinium-based contrast agents can increase the risk of nephrogenic systemic fibrosis (NSF) in patients with acute or chronic severely impaired kidney function either with or without liver impairment, cirrhosis or liver transplant. For more information, speak with your doctor, radiographer or nurse.

GADOVIST® 1.0 (GAD-oh-vist)

Active ingredient: *gadobutrol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GADOVIST 1.0. **You should also speak to your doctor, radiographer, nurse or pharmacist if you would like further information or if you have any concerns or questions about using GADOVIST 1.0.**

Where to find information in this leaflet:

1. Why am I given GADOVIST 1.0?

GADOVIST 1.0 contains the active ingredient gadobutrol.

GADOVIST 1.0 is a contrast agent used during a magnetic resonance imaging (MRI) examination. It aids in the detection of known or suspected abnormalities in the body: brain, spinal cord, blood vessels, head and neck region, chest, breast, abdomen, pelvis, kidneys, bones, muscles and heart.

GADOVIST 1.0 is a liquid that alters the way in which the MRI machine detects certain tissues within the body, often making the pictures clearer and showing things that may not have been visible using MRI alone.

2. What should I know before I am given GADOVIST 1.0?

Warnings

Do not use GADOVIST 1.0 if:

- you are allergic to gadobutrol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor, radiographer or nurse if you have:

- any other allergies (e.g. seafood, hay fever, hives, anaphylaxis)
- very poor kidney function or severe kidney problems
- had a liver transplant, impaired liver function or liver cirrhosis
- bronchial asthma
- severe heart and circulatory disorders
- low threshold for seizures
- a heart pacemaker or any material in your body containing iron
- are taking beta-blockers used for high blood pressure or heart conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

There is no need to stop breastfeeding if you need an examination involving GADOVIST 1.0.

Use in children

GADOVIST 1.0 is approved for use in adults, adolescents and children including full-term newborns.

It is recommended that you do not eat for 2 hours before you are given GADOVIST 1.0.

3. What if I am taking other medicines?

Tell your doctor, radiographer, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with GADOVIST 1.0 and affect how it works.

Tell your doctor, radiographer or nurse if you are taking beta-blockers used for high blood pressure or heart conditions.

If you experience an allergy-like reaction to GADOVIST 1.0, any treatment given to you may be affected by these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GADOVIST 1.0.

4. How am I given GADOVIST 1.0?

How much to be given

- The dosage of GADOVIST 1.0 is based on your weight and area of your body that will be examined. The doctor, radiographer or nurse will calculate the right dose for you.

When GADOVIST 1.0 is given

- GADOVIST 1.0 will be given immediately before or during your MRI examination.

How GADOVIST 1.0 is given

- GADOVIST 1.0 is injected by a small needle into a vein, usually in your hand or arm.
- GADOVIST 1.0 should not be injected into your back.

If you are given too much GADOVIST 1.0

If you think that you have been given too much GADOVIST 1.0, ask the doctor, radiographer or nurse. As GADOVIST 1.0 is given by the doctor, radiographer or nurse, overdose is unlikely. If it does happen, a doctor will treat any symptoms that follow.

If you currently have a problem with your kidneys or liver, the doctor may decide to remove GADOVIST 1.0 from the body by means of a blood-cleansing procedure (dialysis).

You should immediately:

- phone the Poisons Information Centre (**by calling Australia: 13 11 26 or New Zealand 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving GADOVIST 1.0?

Things you should do

Follow carefully the directions given to you by your doctor and other medical staff.

Call your doctor, radiographer or nurse straight away if you:

- experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock
- have very poor kidney function or severe kidney problems
- had a liver transplant, impaired liver function or liver cirrhosis
- have severe heart and circulatory disorders
- have low threshold for seizures.

Remind any doctor, dentist or pharmacist you visit that you have been given GADOVIST 1.0.

Recent information shows that gadolinium (contained in GADOVIST 1.0) may build up in the brain after multiple uses and the effect on the brain is unknown right now. Your doctor will carefully consider whether to use repeated doses and will use the lowest dose of GADOVIST 1.0.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GADOVIST 1.0 affects you.

GADOVIST 1.0 is expected to have little to no effect on the ability to drive and use machines.

Looking after your medicine

- The MRI unit will store GADOVIST 1.0 under the conditions advised by the manufacturer.
- Shelf life and storage conditions are printed on the pack.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

A high level of excitement, anxiety and pain may increase the risk of side effects or make contrast agent related reactions more intense.

Allergic reaction

Some people may experience symptoms of an allergic reaction such as loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.

Allergic reactions occur more frequently in people with a history of allergies to other contrast agents, to foods (e.g. seafood) or those who suffer from anaphylaxis, hay fever or bronchial asthma.

Most of these reactions occur within 30 minutes of receiving GADOVIST 1.0. Rarely, some of these reactions may be delayed (up to several days after receiving GADOVIST 1.0).

Nephrogenic Systemic Fibrosis

If you have very poor kidney function or severe kidney disease, and you receive any gadolinium-containing

contrast agent for an MRI, you may be at risk of developing a rare condition known as Nephrogenic Systemic Fibrosis (NSF). This condition can cause hardening (fibrosis) of the skin and tissues.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders • Nausea • Vomiting • Dry mouth **Nervous system disorders** • Headache • Dizziness • Distaste in mouth • Pins and needles sensation • Unpleasant smells **General disorders** • Feeling hot or cold • Malaise (tired)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Immune system disorders • Experience swelling of the face, eyelids, lips, tongue or other parts of the body • Coughing or throat irritation • Itching or hives • Wheezing, shortness of breath, difficulty breathing, gasping • Gagging, feeling of suffocation • Low blood pressure **Nervous system disorders** • Loss of consciousness • Uncontrolled shaking (convulsions) **Cardiac disorders** • Abnormal heartbeat (maybe faster) • Heart attack **Respiratory or lung disorders** • Difficulty breathing **Skin disorders** • Pale skin • Flushing (skin redness) • Itchy skin • Rash **General disorders** • Injection site reaction • Feeling cold • Rashes, large areas of hardened skin • Weakness, discomfort • Joint pain	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor, radiographer, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration in Australia online at www.tga.gov.au/reporting-problems or in New Zealand https://nzphvc.otago.ac.nz/reporting/ . By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available in an MRI unit.

What GADOVIST 1.0 contains

Active ingredient (main ingredient)	Gadobutrol
Other ingredients (inactive ingredients)	Calcobutrol sodium Trometamol Hydrochloric acid Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What GADOVIST 1.0 looks like

GADOVIST 1.0 is a clear, colourless to slightly yellow 1.0 mmol/mL solution for injection and is supplied in glass vials and glass or plastic pre-filled syringes of various sizes.

Glass vial and pre-filled syringes:
2 mL vial – AUST R 286854
7.5 mL vial – AUST R 67048
15 mL vial – AUST R 67047
30 mL vial – AUST R 72494
65 mL bottle – AUST R 416320
5 mL syringe – AUST R 72493
7.5 mL syringe – AUST R 67046
10 mL syringe – AUST R 72518

Plastic pre-filled syringes:
5 mL syringe – AUST R 72493
7.5 mL syringe – AUST R 67046
10 mL syringe – AUST R 72518

Not all presentations may be marketed in Australia or New Zealand.

Who distributes GADOVIST 1.0

Bayer Australia Limited
ABN 22 000 138 714

875 Pacific Highway
Pymble NSW 2073
www.bayer.com.au

Bayer New Zealand Limited
PO Box 2825
Shortland Street
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This leaflet was prepared in July 2024.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information or on the Medsafe website (www.medsafe.govt.nz) for New Zealand.