

GADOVIST® 1.0

(GAD·oh·vist)

gadobutrol

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Gadovist 1.0. It does not contain all the available information. It does not take the place of talking to your doctor or health care professional.

All diagnostic agents have risks and benefits. Your doctor has weighed the risks of you using Gadovist 1.0 against the benefits it is expected to have for you.

If you have any concerns about using this diagnostic agent, ask your doctor or radiologist.

Keep this leaflet.

You may need to read it again.

WHAT GADOVIST 1.0 IS USED FOR

Gadovist 1.0 is used at the same time as magnetic resonance imaging (MRI) to aid 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 for use in adults, adolescents and children including full-term newborns.

MRI is a form of medical diagnostic imaging that forms pictures after detecting water molecules in normal and abnormal tissues. This is done using a complex system of magnets and radiowaves.

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

Gadovist 1.0 is only available at MRI units for use in conjunction with MRI.

Ask your doctor if you have any questions about why Gadovist 1.0 is being used in you.

Your doctor may be using it for another reason.

BEFORE YOU ARE GIVEN GADOVIST 1.0

When you must not be given it

Your radiologist will assess if it is appropriate for you to be administered Gadovist 1.0.

You must not be given Gadovist 1.0 if you have an allergy to:

- gadobutrol, the active ingredient in Gadovist 1.0, or
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, throat, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given Gadovist 1.0 after the expiry date printed

on the pack or if the packaging is torn or shows signs of tampering. The doctor will check this for you.

Before you are given it

Tell your doctor if you have allergies to any medicines, foods, preservatives or dyes.

Tell your doctor if you are allergic to diagnostic agents. Allergy like reactions may occur after use of Gadovist 1.0.

In some cases you may need special care with Gadovist 1.0 and your doctor will need to consider whether to give you Gadovist 1.0.

Recent information shows that gadolinium (as 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
- use the lowest dose

Tell your doctor if you have, or have had, any medical conditions especially the following:

- very poor kidney function or severe kidney problems
- a liver transplant
- any allergies e.g. seafood allergies, hay fever, hives)
- bronchial asthma
- severe heart and circulatory disorders
- a low threshold for seizures.

Tell your doctor if you are pregnant, or think you may be pregnant.

Your doctor can discuss with you the risks and benefits involved.

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

Tell your doctor if you have a heart pacemaker or any material containing iron implanted in your body.

If you have not told your doctor about any of the above, tell him/her before you are given Gadovist 1.0.

Taking other medicines

Tell your doctor if you are taking any medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- beta-blockers (medicines used to treat high blood pressure or other heart conditions).

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

Your doctor/radiologist has more information on medicines to be careful with or avoid while receiving Gadovist 1.0.

HOW GADOVIST 1.0 IS GIVEN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

It is recommended that you do not eat for 2 hours before the use of Gadovist 1.0.

If you do not understand the instructions you have been given, ask your doctor.

How much is given

The actual dosage of Gadovist 1.0 that is right for you will be worked out by the radiologist and will

depend on the region of your body to be examined and your weight.

How it is given

Gadovist 1.0 is injected via a small needle into a vein, usually in the back of your hand or in front of your elbow.

When it is given

Gadovist 1.0 will be administered immediately before your MRI examination.

If you are given too much (overdose)

As Gadovist 1.0 is administered by a doctor, overdose is unlikely. If it does happen, the 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).

Immediately tell your doctor or other medical staff or telephone the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have been given too much Gadovist 1.0.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

AFTER HAVING GADOVIST 1.0

Things you must do

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

Things to be careful of

Tell your doctor if you are going to have any laboratory tests.

SIDE EFFECTS

Tell your doctor as soon as possible if you do not feel well whilst receiving or after being given Gadovist 1.0.

All contrast media can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following after injection of Gadovist 1.0 and they worry you:

- headache
- dizziness
- nausea.

The above list includes the more common side effects of Gadovist 1.0. They are usually mild and short-lived. If they persist or get worse, tell your doctor.

Tell your doctor immediately if you notice any of the following:

- 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
- abnormal heart beat (maybe faster)
- uncontrolled shaking (convulsions)
- unpleasant smells
- loss of consciousness
- low blood pressure
- pale skin
- flushing (redness)
- weakness, discomfort
- feeling cold

- large areas of hardened skin
- joint pain.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Some of these side effects could be the first signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

Allergic reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur, causing low blood pressure, loss of consciousness or heart attack, increase in heart rate, difficulty breathing, and swelling of the face, lips or tongue leading to severe breathing difficulties and shock may occur.

Tell the doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Rarely, delayed reactions can occur.

PRODUCT DESCRIPTION

Storage

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.

What it 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.

Ingredients

Active ingredients:

- gadobutrol (604.72 mg/mL)

Inactive ingredients:

- calcobutrol sodium
- trometamol
- hydrochloric acid
- water for injections

Supplier

Made in Germany for:

Bayer Australia Limited
 ABN 22 000 138 714
 875 Pacific Highway
 Pymble NSW 2073

Bayer New Zealand Limited
 3 Argus Place, Hillcrest,
 North Shore
 Auckland 0627

Australian registration number

Gadovist 1.0 AUST R numbers:

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
- 5 mL syringe – AUST R 72493
- 7.5 mL syringe – AUST R 67046
- 10 mL syringe – AUST R 72518
- 15 mL syringe – AUST R 67045
- 20 mL syringe – AUST R 72517

Plastic pre-filled syringes:

- 5 mL syringe – AUST R 72493
- 7.5 mL syringe – AUST R 67046
- 10 mL syringe – AUST R 72518
- 15 mL syringe – AUST R 67045
- 20 mL syringe – AUST R 72517

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

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You can find the latest Consumer Medicine Information on the TGA website (www.ebs.tga.gov.au) for Australia or on the MEDSAFE website (www.medsafe.govt.nz) for New Zealand.

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