

# PRIMOVIST®

## 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 PRIMOVIST?

PRIMOVIST contains the active ingredient disodium gadoxetate. PRIMOVIST is a contrast agent used during a magnetic resonance imaging (MRI) examination of the liver in adults.

For more information, see Section [1. Why am I given PRIMOVIST?](#) in the full CMI.

### 2. What should I know before I am given PRIMOVIST?

Do not use if you have ever had an allergic reaction to PRIMOVIST 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.**

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

For more information, see Section [2. What should I know before I am given PRIMOVIST?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PRIMOVIST 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 PRIMOVIST?

PRIMOVIST is injected into your vein by a doctor, radiographer or nurse during your MRI examination.

More instructions can be found in Section [4. How am I given PRIMOVIST?](#) in the full CMI.

### 5. What should I know while receiving PRIMOVIST?

<b>Things you should do</b>	<p>Tell your doctor, radiographer or nurse if you:</p> <ul style="list-style-type: none"><li>• 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</li><li>• have very poor kidney function or severe kidney problems</li><li>• had a liver transplant, impaired liver function or liver cirrhosis</li><li>• have severe heart and circulatory disorders or abnormal heart rhythm</li><li>• are on a low sodium diet.</li></ul>
<b>Looking after your medicine</b>	<p>The MRI unit will store PRIMOVIST as required by the manufacturer.</p>

For more information, see Section [5. What should I know while receiving PRIMOVIST?](#) 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 and nephrogenic systemic fibrosis (NSF). Common side effects can include nausea, headache, feeling hot, increased blood pressure 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.**

# PRIMOVIST<sup>®</sup> (PREE-moh-vist)

Active ingredient: *disodium gadoxetate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PRIMOVIST. **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 PRIMOVIST.**

Where to find information in this leaflet:

- [1. Why am I given PRIMOVIST?](#)
- [2. What should I know before I am given PRIMOVIST?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given PRIMOVIST?](#)
- [5. What should I know while receiving PRIMOVIST?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I given PRIMOVIST?

PRIMOVIST contains the active ingredient disodium gadoxetate.

PRIMOVIST is a contrast agent used during a magnetic resonance imaging (MRI) examination. It aids in the detection of known or suspected abnormalities in the liver.

PRIMOVIST is a liquid that alters the way in which the MRI machine detects certain lesions in the liver, 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 PRIMOVIST?

#### Warnings

Do not use PRIMOVIST if:

- you are allergic to disodium gadoxetate, 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 or abnormal heart rhythm
- a heart pacemaker or any material in your body containing iron
- are taking beta-blockers used for high blood pressure or heart conditions
- are taking medicines which affect your heart rhythm
- are taking medicines used to treat infections (such as rifampicin)
- a low sodium diet
- 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?](#)

**It is recommended that you do not eat for 2 hours before you are given PRIMOVIST.**

#### 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 PRIMOVIST.

#### Use in children

PRIMOVIST is not recommended for use in children and adolescents below 18 years.

### 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 PRIMOVIST 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
- medicines that affect the rhythm of the heart
- medicines used to treat infections (such as rifampicin).

If you experience an allergy-like reaction to PRIMOVIST, 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 PRIMOVIST.**

## 4. How am I given PRIMOVIST?

### How much to be given

- The dosage of PRIMOVIST is based on your weight. The doctor, radiographer or nurse will calculate the right dose for you.

### When PRIMOVIST is given

- PRIMOVIST will be given during your MRI examination.
- A scan may start before and immediately after the PRIMOVIST injection and any additional scans may take up to 120 minutes after your injection.

### How PRIMOVIST is given

- PRIMOVIST is injected by a small needle into a vein, usually in your hand or arm.

### If you are given too much PRIMOVIST

If you think that you have been given too much PRIMOVIST, ask the doctor, radiographer or nurse. As PRIMOVIST 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 PRIMOVIST 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 PRIMOVIST?

### Things you should do

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

**Tell your doctor, radiographer or nurse if you are on a low sodium diet.**

### 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 or abnormal heart rhythm.

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

Recent information shows that gadolinium (contained in PRIMOVIST) 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 PRIMOVIST.

### Laboratory tests

**If you are to have any blood tests, tell your doctor you have received PRIMOVIST.**

PRIMOVIST may alter the results of iron and bilirubin levels detected in a blood test for 1 to 4 days after your scan.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how PRIMOVIST affects you.**

It is not known whether PRIMOVIST has an effect on the ability to drive and use machines.

### Looking after your medicine

- The MRI unit will store PRIMOVIST 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.

### 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 PRIMOVIST. Rarely, some of these reactions may be delayed (up to several days after receiving PRIMOVIST).

### 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
<b>Gastrointestinal disorders</b> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Dry mouth</li> <li>• More saliva production</li> </ul> <b>Nervous system disorders</b> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> <li>• Distaste in mouth</li> <li>• Pins and needles sensation</li> <li>• Unpleasant smells</li> <li>• Tremor</li> <li>• Restlessness</li> </ul> <b>Vascular disorders</b> <ul style="list-style-type: none"> <li>• Flushing</li> </ul> <b>Skin disorders</b> <ul style="list-style-type: none"> <li>• Itchy skin</li> <li>• Rash</li> <li>• Sweaty skin</li> </ul> <b>Musculoskeletal disorders</b> <ul style="list-style-type: none"> <li>• Back pain</li> </ul> <b>General disorders</b> <ul style="list-style-type: none"> <li>• Feeling hot</li> <li>• Chills</li> <li>• Feeling abnormal or discomfort</li> <li>• Malaise (tired)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<b>Immune system disorders</b> <ul style="list-style-type: none"> <li>• Experience swelling of the face, eyelids, lips, tongue or other parts of the body</li> <li>• Coughing or throat irritation, sneezing</li> <li>• Itching or hives</li> <li>• Wheezing, shortness of breath, difficulty breathing, gasping</li> <li>• Gagging, feeling of suffocation</li> <li>• Low blood pressure, pale skin</li> </ul> <b>Respiratory disorders</b>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>• shortness of breath, difficulty breathing, gasping</li> </ul> <b>Cardiac disorders</b> <ul style="list-style-type: none"> <li>• Faster heartbeat</li> <li>• Abnormal heart rhythm</li> </ul> <b>General disorders</b> <ul style="list-style-type: none"> <li>• Injection site reaction</li> </ul>	
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**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](http://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 PRIMOVIST contains

<b>Active ingredient (main ingredient)</b>	Disodium gadoxetate
<b>Other ingredients (inactive ingredients)</b>	Trometamol Trisodium caloxetate Hydrochloric acid (for pH) Sodium hydroxide (for pH) Water for injections

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

### What PRIMOVIST looks like

PRIMOVIST is a clear, colourless to slightly yellow 0.25 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:

5 mL vial – AUST R 102088

7.5 mL vial – AUST R 104374

10 mL vial – AUST R 104379

5 mL syringe – AUST R 102089

7.5 mL syringe – AUST R 104380

10 mL syringe – AUST R 104381

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

## Who distributes PRIMOVIST

Bayer Australia Limited  
ABN 22 000 138 714  
875 Pacific Highway  
Pymble NSW 2073  
[www.bayer.com.au](http://www.bayer.com.au)

Bayer New Zealand Limited  
PO Box 2825  
Shortland Street  
Auckland 1140  
New Zealand  
Free phone 0800 229 376

This leaflet was prepared in December 2020.

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



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