

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about Primovist. It does not contain all available information. It does not take the place of talking to your doctor.

All diagnostic agents have risks and benefits. Your doctor has weighed the risks of you using Primovist against the benefits they expect it will 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 PRIMOVIST IS USED FOR

Primovist is used to help detect and diagnose changes that may be found in the liver. Abnormal signs within the liver can be better evaluated. Primovist can also help the doctor determine the nature of any abnormalities, thereby increasing the confidence one can have in the diagnosis. The diagnosis can be made quicker, earlier, and with greater accuracy than without using Primovist.

Primovist is used together with an imaging technique called magnetic resonance imaging (MRI). MRI is a form of medical diagnostic imaging that distinguishes between normal and abnormal tissues without using x-rays.

Primovist is a magnetic liquid that alters the way in which tissues appear, showing abnormalities that may not be visible using MRI alone.

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

Primovist is for diagnostic use only.

Ask your doctor/radiologist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU ARE GIVEN PRIMOVIST

When you must not be given it

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

- disodium gadoxetate, the active ingredient in Primovist
- 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, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given Primovist 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.

If you are not sure whether you should be given this diagnostic agent, talk to your doctor.

Before you are given it

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

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

Your doctor might check your kidney function before giving Primovist.

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

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

- severe heart problems
- kidney problems
- any allergies
- bronchial asthma.

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

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

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

Tell your doctor if are on a low sodium diet.

The use of PRIMOVIST in patients younger than 18 years is not recommended because no clinical experience is available.

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

Taking other medicines

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

Some medicines and Primovist may interfere with each other. These include:

- medicines to treat high blood pressure
- medicines that affect the rhythm of the heart
- medicines to treat infections (such as rifampicin)

These medicines may be affected by Primovist or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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

HOW PRIMOVIST IS GIVEN

How much is given

The dose of Primovist varies depending on your weight. The doctor will decide how much Primovist is needed for your examination.

How it is given

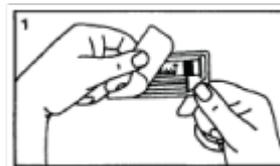
You will be asked to lie down on the MRI scanning bed and then you will be given Primovist by injection into a vein. The usual injection site is the back of your hand or just in front of your elbow.

When it is given

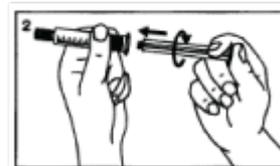
Scanning may start immediately after the Primovist injection. After the injection you will be observed for at least 30 minutes.

How to prepare the PRIMOVIST syringe for injection

Glass syringe only:



Peel the cover from the syringe tray and take the syringe and plunger rod out of the package.



Screw the plunger into the syringe tightly



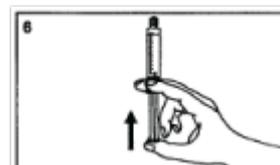
Break the first part of the protective grey cap



Remove the protective grey cap from the tip of the syringe



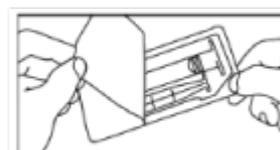
Remove the black stopper from the second part of the grey cap



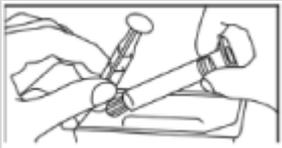
Remove the air in the syringe

Plastic syringe only:

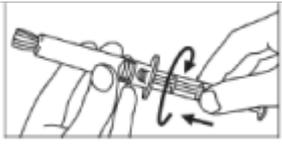
Hand injection:



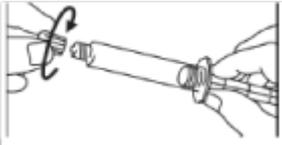
1. Open the package



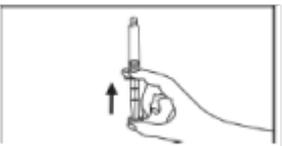
2. Take the syringe and plunger rod out of the package



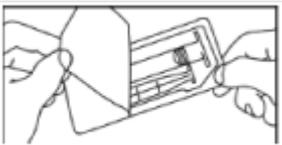
3. Screw the plunger rod into the syringe



4. Unscrew the cap from the syringe



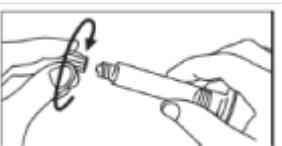
5. Remove the air in the syringe
Injection with a power injector:



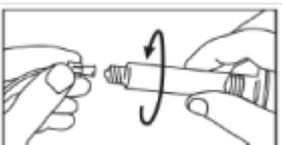
1. Open the package



2. Take the syringe out of the package



3. Unscrew the cap from the syringe



4. Connect the tip of the syringe onto the tubing system and follow the device manufacturer's instructions

If you take are given too much (overdose)

As Primovist 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

Primovist from the body by means of a blood-cleansing procedure (dialysis).

If in doubt it is recommended to 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 Primovist. Do this even if there are no signs of discomfort or poisoning.

AFTER YOU ARE GIVEN PRIMOVIST

Things you must do

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

You may also be advised to take fluids before and after the procedure to help protect your kidneys.

Things to be careful of

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

Be careful when driving or operating machinery until you know how Primovist affects you.

SIDE EFFECTS

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

All diagnostic agents 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.

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 and they worry you:

- headache
- nausea
- feeling hot
- dizziness

The above list includes the more common side effects of Primovist. 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
- watering, sore or inflamed eyes
- sneezing, runny nose, coughing or throat irritation
- itching or hives
- difficulty breathing, gasping
- decrease sense of touch or sensation
- pale skin

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, increase in heart rate, difficulty breathing, and swelling of the face, lips or tongue leading to severe breathing difficulties and shock may occur.

Tell your 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.

STORING PRIMOVIST

Storage

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

PRODUCT DESCRIPTION

What it looks like

Primovist is supplied in glass vials or glass pre-filled syringes or plastic pre-filled syringes.

Ingredients

Active ingredients:

- Primovist – contains 181.43 mg (250 µmol) of disodium gadoxetate

Inactive ingredients:

- trisodium caloxetate
- trometamol
- hydrochloric acid
- sodium hydroxide
- water for injections

Australian Registration Number

Primovist 5mL vial - AUST R 102088

Primovist 5mL pre filled syringe - AUST R 102089

Primovist 7.5mL vial - AUST R 104374

Primovist 7.5mL pre filled syringe - AUST R 104380

Primovist 10mL vial - AUST R 104379

Primovist 10mL pre filled syringe - AUST R 104381

Supplier

Made in Germany for:

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

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

Date of Preparation

October 2017

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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