APPLICANT: BAYER (PTY) LTD
PRODUCT NAME: Primovist
DOSAGE FORM: Solution of injection
STRENGTHS: 5ml/7.5ml/10ml

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PRIMOVIST 5ml, 7.5ml, 10ml

Gadoxetic acid disodium

Read all of this leaflet carefully before you start using PRIMOVIST

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PRIMOVIST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even of their symptoms are the same as yours.

What is in this leaflet

1. What PRIMOVIST is and what is used for.
2. What you need to know before you use PRIMOVIST
3. How to use PRIMOVIST
4. Possible side effects
5. How to store PRIMOVIST
6. Contents of the pack and other information.

1. What PRIMOVIST is and what it is used for

Primovist is a contrast medium for MRI of the liver.

It is used to help detect and diagnose changes that may be found in the liver. Abnormal signs within the liver can be better evaluated (as to number, size, and distribution). Primovist can also help the doctor determine the nature of any abnormalities, thereby increasing the confidence one can have in the diagnosis.

It is provided as a solution for intravenous injection. This medicine is for diagnostic use only.

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

2. What you need to know before you use PRIMOVIST

Do not use PRIMOVIST

If you have known hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions

- If you are allergic (hypersensitive) to gadoxetic acid disodium or any of the other ingredients of Primovist (see section '*Contents of the pack and other information'*)
- If you had a previous reaction to contrast media
- If you have had allergy (e.g. hay fever, hives) or asthma
- If you have a severe disease of the heart and blood vessels
- If you have a very poor kidney function
- If you have recently had, or soon expect to have, a liver transplant

- Before you receive Primovist **tell your doctor if any of these applies to you.** Your doctor will decide whether the intended examination is possible or not.

Allergy-like reactions may occur after use of Primovist. Severe reactions are possible. Most of these reactions occur within 30 minutes after administration. Therefore, you will be observed for at least 30 minutes after the injection.

Delayed reactions may occur hours or even days later (see section '*Possible side effects'*).

Kidney impairment:

- Before you receive Primovist, **your doctor will check how well your kidneys are working**. Your doctor may decide to take a blood test to check this before making the decision to use Primovist

If you have a poor kidney function, the doctor will make sure that Primovist has been eliminated from your body before you receive a second injection of Primovist.

Primovist can be removed from the body by dialysis. If you are already undergoing regular dialysis, your doctor will give a recommendation when to schedule the next dialysis.

There have been reports of a severe reaction, mainly involving a thickening of the skin and connective tissues (nephrogenic systemic fibrosis (NSF)). NSF may result in severe joint immobility, muscle weakness or may affect the normal working of internal organs which may potentially be life-threatening.

NSF has been associated with the use of some contrast agents containing gadolinium in patients with severe kidney impairment.

It has also been associated with the use of some contrast agents containing gadolinium in patients with acute kidney insufficiency due to the hepato-renal syndrome (kidney failure in patients with advanced chronic liver disease) or in patients with acute kidney insufficiency, who have recently had or soon expect to have a liver transplant (see section '*Possible side effects'*).

If any of this applies to you, your doctor will only administer Primovist after careful consideration.

Other medicines and Primovist

- **Tell your doctor** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These include especially:

- Rifampicin (medicine used to treat infections, such as tuberculosis)

PRIMOVIST with food and drinks

Not applicable

Pregnancy and breastfeeding

Pregnancy:

Tell your doctor if you think you are or might become pregnant as Primovist should only be used during pregnancy if it is strictly necessary.

Breastfeeding:

There is no need to stop breastfeeding if you need an examination involving Primovist. No effects on the infant are anticipated when Primovist is used with the recommended doses.

Driving and using machines

Not applicable

What Primovist contains

- **The active substance is** gadoxetic acid disodium . Each ml of solution for injection contains 0.25 mmol gadoxetic acid disodium (equivalent to 181.43 mg gadoxetic acid disodium).
- **The other ingredients are** caloxetate trisodium; hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), trometamol and water for injection

3. How to use PRIMOVIST

Primovist is injected by a doctor via a needle or catheter into your vein. Your MRI examination can start immediately.

The actual dosage of Primovist that is right for you will depend on your body weight:

A single injection of 0.1 ml Primovist per kg body weight is generally sufficient (this means, for a person weighing 70 kg the dose would be 7 ml).

No dosage adjustment is necessary for patients with poor kidney function (see section *'Warnings and precautions'*).

Further information regarding the administration and handling of Primovist is given at the end of this leaflet (see section '*Contents of the pack and other information'*).

If you receive more Primovist than you should

No overdosing has so far been reported. If it does happen, the doctor will treat any resulting symptoms and will check whether your kidneys are working normally.

If you have any further questions on the use of this product, ask your doctor or radiologist.

4. Possible side effects

Like all medicines, Primovist can cause side effects, although not everybody gets them.

Most of the side effects are mild to moderate.

The most frequently observed side effects in patients receiving Primovist (may affect 5 or more in a 1,000 users) are nausea (feeling sick), headache, feeling hot, high blood pressure and dizziness.

The most serious side effect in patients receiving Primovist is anaphylactoid shock (a severe allergy-like reaction).

In rare cases **allergy-like reactions** may occur, including severe reactions (shock) that may need immediate medical intervention.

If you notice:

- mild swelling of the face, lips, tongue or throat
- coughing or sneezing
- difficulty in breathing
- itching
- runny nose
- hives (nettle-type rash)

tell the MRI department staff immediately. They may be the first signs that a severe reaction is happening. Your investigation may need to be stopped and you may need further treatment.

Delayed allergy-like reactions, hours to several days after the administration of Primovist, have been observed in rare cases. If this should happen to you, tell your doctor or radiologist.

Below we list reported/experienced side effects by frequency

Common: affects 1 to 10 users in 100

- headache
- nausea (feeling sick)

Uncommon: affects 1 to 10 users in 1,000

- vertigo (sensation of whirling)
- dizziness

- dysgeusia (disturbed sense of taste)
- paraesthesia ("pins and needles")
- parosmia (disturbed sense of smell)
- high blood pressure
- flushing
- dyspnoea, respiratory distress (difficulty in breathing)
- vomiting
- dry mouth
- rash
- pruritus (severe itching of the skin or eyes)
- back pain
- chest pain
- various kinds of injection site reactions including extravasation (involuntary leakage of the contrast agent and bleeding), burning, coldness, irritation, pain
- feeling hot
- chills
- fatigue (tiredness)
- feeling abnormal

Rare: affects 1 to 10 users in 10,000.

- tremor
- akathisia (restlessness)
- bundle branch block (heart block)
- palpitation (irregular, rapid beating or pulsation of the heart)
- oral discomfort (discomfort of the mouth)
- salivary hypersecretion (increased production of saliva)
- maculopapular rash (measle-like rash)
- hyperhidrosis (excessive sweating)
- discomfort
- malaise (generally feeling unwell)

Not known (frequency cannot be estimated from the available data)

hypersensitivity/anaphylactoid (allergy-like) reaction, e.g.

- shock
- hypotension (low blood pressure)
- pharyngolaryngeal oedema (swelling in the tongue or throat)
- urticaria (hives, nettle-type rash)
- face oedema(swelling of the face)
- rhinitis (runny nose)
- conjunctivitis

  - abdominal pain (stomach pain)
  - hypoesthesia (reduced feeling or sensitivity in the skin)
  - sneezing
  - cough
  - pallor (pale skin)
- restlessness
- tachycardia (increase in heart rate)

The following side effects have been life-threatening or fatal in some cases: shock and dyspnoea (difficulty in breathing).

Slightly altered laboratory values of iron and bilirubin may occur for a short period after you have been given Primovist. Therefore, inform the health personnel that you have recently undergone an examination with Primovist if you need to have blood samples taken.

- **If any of the side effects gets serious**, or if you notice any side effects not listed in this leaflet, please tell your doctor or radiologist.

There have been reports of nephrogenic systemic fibrosis (a disease mainly involving thickening of the skin and connective tissues) associated with use of some contrast agents containing gadolinium (see section '*Warnings and precautions*').

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications : https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PRIMOVIST.

5. How to store Primovist

Store at or below 30 °C.
From a microbiological point of view, the product should be used immediately after opening.

6. Contents of the pack and other information

What Primovist contains

- **The active substance is** gadoxetic acid disodium . Each ml of solution for injection contains 0.25 mmol gadoxetic acid disodium (equivalent to 181.43 mg gadoxetic acid disodium).

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What PRIMOVIST looks like and what it contains

Clear, colourless to pale yellow solution, free of particles.

Cartons of 1, 5 or 10 containing:

- vials of 5 ml, 7,5 ml or 10 ml – colourless glass type 1, with a black chlorinated butyl rubber stopper and an aluminium lacquered cap with a pink polypropylene plastic cap; or
- pre-filled syringes of 5 ml, 7,5 ml or 10 ml – colourless glass type 1, with a plunger stopper and tip cap of black chlorinated butyl rubber.

Holder of certificate of registration

Bayer (Pty) Ltd
(Reg No: 1968/011192/07)
27 Wrench Road
ISANDO
1609

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