PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
GADOVIST
Solution for injection

- **Read all of this leaflet carefully before you are given GADOVIST.**
- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**

1. WHAT GADOVIST CONTAINS:

The active substance is gadobutrol 604,72 milligram corresponding to 1 millimol per millilitre.
The other ingredients are calcobutrol sodium, hydrochloric acid, trometamol, and water for injections.

2. WHAT GADOVIST IS USED FOR:

GADOVIST is a contrast medium for magnetic resonance imaging (MRI) of the different regions in the body. MRI is a form of medical diagnostic imaging that delivers pictures using the behaviour of water molecules in normal and abnormal tissues. This is done by a complex system of magnets and radiowaves.

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

GADOVIST is for use in adults and children of all ages including **full-term newborns**.

3. BEFORE YOU are given GADOVIST:

You should not be given GADOVIST:

If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding"). Breastfeeding should be stopped for at least 24 hours after you have received GADOVIST.

Take special care with GADOVIST:
Allergy-like hypersensitivity reactions involving the heart, breathing or the skin, may occur with the use of GADOVIST. Severe reactions including shock are possible. Most of these reactions occur within at least half an hour of administration. However, cases of delayed reactions (after hours to days) may occur (see "POSSIBLE SIDE EFFECTS").

Before you are given GADOVIST **tell your doctor if any of the conditions listed below apply to you**. Your doctor will decide whether the intended examination is possible or not.

- If you are allergic (hypersensitive) to gadobutrol or any of the other ingredients of GADOVIST.
- If you had a previous reaction to contrast media.
- If you suffer or have suffered from an allergy (e.g. hay fever, hives) or asthma.
- If you have a severe disease of the heart and blood vessels.
- If you suffer from brain conditions with seizures (fits).

Tell your doctor if you have a heart pacemaker or if there are any implants or clips containing iron in your body.

There have been reports of a severe reaction, mainly involving a hardening of the skin and body areas (*nephrogenic systemic fibrosis (NSF)*), associated with the use of GADOVIST in patients with severe kidney impairment or acute kidney insufficiency.

Your doctor may decide to **take a blood test to check how well your kidneys are working** before making the decision to use GADOVIST.
If you have a poor kidney function, your doctor will make sure that GADOVIST has been eliminated from your body before you receive a second injection of GADOVIST.
GADOVIST can be removed from the body by dialysis. If you have a poor kidney function your doctor will decide if you should receive dialysis after you have been given GADOVIST.

Using GADOVIST with food and drink:
GADOVIST can cause nausea and vomiting. You will therefore be asked not to eat anything for 2 hours before the examination.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice.

Pregnancy:

Tell your doctor if you are pregnant or could be pregnant, since GADOVIST should not be used during pregnancy. The safe use of GADOVIST during pregnancy has not yet been demonstrated.

Breastfeeding:

Tell your doctor if you are breastfeeding or intend to breastfeed since breastfeeding should be stopped for at least 24 hours following GADOVIST administration.

Using other medicines with GADOVIST:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GADOVIST with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Inform your doctor specifically if you are taking beta blockers (medication for treating hypertension or irregular heartbeat).

4. HOW GADOVIST IS USED:

GADOVIST is injected by a doctor via a needle into a vein. GADOVIST will be administered immediately before your MRI examination. After the injection you will be observed.
The actual dosage of GADOVIST that is right for you will depend on your body weight and on the region of examination.

If you receive more GADOVIST than you should:
Overdosing is unlikely. If it does happen, the doctor will treat any symptoms that follow.
In some cases the doctor will check whether your heart and kidneys work properly.

5. POSSIBLE SIDE EFFECTS:

GADOVIST can cause side effects.

Not all side effects reported for GADOVIST are included in this leaflet.
Should your general health worsen while using GADOVIST, please consult your doctor, pharmacist or other healthcare professional for advice.

The **most serious side effects** (which have been fatal or life-threatening in some cases) are: cardiac arrest (heart stops beating) and severe anaphylactoid (allergy-like) reactions.

In addition for the **following side effects life-threatening or fatal outcomes** has been observed in some cases: dyspnoea (shortness of breath) and loss of consciousness (fainting).

In some cases **allergy-like reactions** may occur, including severe reactions that may need immediate medical intervention.
Allergy-like reactions (hypersensitivity and anaphylaxis) have been reported, including severe reactions (shock) that may need immediate medical intervention. Swelling of the face, lips, tongue or throat, coughing, itching, runny nose, sneezing and hives (nettle-type rash) may be the first signs that a severe reaction is happening.

Delayed reactions, hours to several days after the administration of GADOVIST, may occur.
Tell the department staff immediately if you experience any of these signs or have difficulty in breathing.

Frequent side effects:
- headache
- Nausea (feeling sick)

Less Frequent side effects:
- allergy-like (hypersensitivity/anaphylactoid) reaction, e.g.
- hypotension (low blood pressure)
- urticaria (hives)
- face oedema (swelling of the face)
- eyelid oedema (swelling of the eyelid)
- flushing

The frequency of the following allergy-like reactions is not known:
- anaphylactoid shock (a severe allergy-like reaction),
- circulatory collapse (shock)
- respiratory arrest (breathing stops)
- pulmonary oedema (fluids in the lungs)
- bronchospasm (breathing difficulties)
- cyanosis (blueness of the lips)
- oropharyngeal swelling (swelling of the mouth and throat)
- laryngeal oedema (swelling of the throat)
- increased blood pressure
- chest pain
- angioedema (e.g. swelling of the face, throat, mouth, lips and/or tongue
- conjunctivitis
- hyperhidrosis (increased sweating)
- cough
- sneezing
- burning sensation
- pallor (pale skin)
- dizziness, dysgeusia (disturbed sense of taste), paresthesia (“pins and needles”)
- dyspnoea (shortness of breath)
- vomiting
- erythema (redness of the skin)
- pruritus (including generalised pruritus) (itching)
- rash [including generalised rash, macular rash (small flat red spots), popular rash small, raised circumscribed lesions), pruritic rash (itchy rash)]
- various kind of injection site reactions (e.g. leakage into the surrounding tissue, burning, coldness, warmth, reddening, rash, pain or bruising)
- feeling hot
- loss of consciousness (fainting)
- convulsions
- parosmia (disturbed sense of smell)
- tachycardia (rapid heartbeat)
- palpitations
- dry mouth

- malaise (generally feeling unwell)
- feeling cold

The frequency for the following side effects cannot be estimated from available data:

- cardiac arrest (heart stops beating)
- nephrogenic systemic fibrosis (NSF)(a disease involving thickening of the skin and connective tissues). NSF may result in severe joint immobility, muscle weakness or may affect the normal working of internal organs which may potentially be life threatening (See "Take special care with GADOVIST")

Children and adolescents:
Type and severity of side effects in children of all ages including full-term newborns are consistent with the side effects profile known in adults.

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

6. STORING AND DISPOSING OF GADOVIST:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Until required for use, GADOVIST must be stored in the original outer carton at or below 30 °C.
Protect from light.
Do not use after the expiry date stated on the carton and the container label.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF GADOVIST:

Clear glass vials of 7,5 ml, 15 ml and 30 ml.
Clear glass prefilled syringes of 7,5 ml, 10 ml and 15 ml.
Clear glass bottles of 65 ml.
Plastic prefilled syringe of 7,5 ml, 10 ml, 15 ml, 20 ml.

8. IDENTIFICATION OF GADOVIST:

Solution – clear, free of particles.

9. REGISTRATION NUMBERS:

GADOVIST 7,5 ml: 34/28/0383
GADOVIST 10 ml: 34/28/0384
GADOVIST 15 ml: 34/28/0385
GADOVIST 30 ml: 34/28/0386
GADOVIST 65 ml: 34/28/0387

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

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

11. DATE OF PUBLICATION:

Date of on the registration certificate of the medicine: 10/04/2002
Date of most recently revised patient information leaflet as approved by Council:
20 March 2018