



Gadovist®

(Gadobutrol)

Package leaflet: Information for the patient
Gadovist 1 mmol/ml solution for injection in
prefilled syringe

Gadobutrol

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or the person giving you Gadovist (the radiologist) or the hospital/MRI-centre personnel.
- If you get any side effects talk to your doctor or radiologist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gadovist is and what it is used for
2. What you need to know before you are given Gadovist
3. How Gadovist will be given
4. Possible side effects
5. How to store Gadovist
6. Contents of the pack and other information

1. WHAT GADOVIST IS AND WHAT IT IS USED FOR

Gadovist is a contrast medium for magnetic resonance imaging (MRI) used for diagnostics of the brain, spine and vessels. Gadovist can also help the doctor find out the kind (benign or malignant) of known or suspected abnormalities in the liver and kidneys.

Gadovist can also be used for MRI of abnormalities of other body regions.

It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and diseased tissue.

It is for use in adults and children of all ages (including term newborn infants).

How Gadovist works

MRI is a form of medical diagnostic imaging that uses the behaviour of water molecules in normal and abnormal tissues. This is done by a complex system of magnets and radio waves. Computers record the activity and translate that into images.

Gadovist is given as an injection into your vein. This medicine is for diagnostic use only and will only be administered by healthcare professionals experienced in the field of clinical MRI practice.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN GADOVIST

Do NOT use Gadovist if you

- are allergic to gadobutrol or any of the other ingredients of this medicine (listed in section 6).
- Warnings and precautions**
- Talk to your doctor before you are given Gadovist if you
 - suffer or have suffered from an allergy (e.g. hay fever, hives) or asthma
 - had a previous reaction to any contrast media
 - have very poor kidney function
 - suffer from brain conditions with seizures (fits) or from other diseases of the nervous system
 - have a heart pacemaker or if there are any implants or clips containing iron in your body.
- Your doctor will decide whether the intended examination is possible or not.
- Allergy-like reactions leading to heart problems, breathing difficulties or skin reactions may occur after use of Gadovist. Severe reactions are possible. Most of these reactions occur within half an hour after you are given Gadovist. Therefore, you will be observed after the examination. Delayed reactions have been observed (after hours or days) (see section 4).

Kidneys/Liver

Tell your doctor if

- your kidneys do not work properly
- you have recently had, or soon expect to have, a liver transplant.

Your doctor may decide to take a blood test to check how well your kidneys are working before making the decision to use Gadovist, especially if you are 65 years of age or older.

Neonates and infants

As kidney function is immature in babies up to 4 weeks of age and infants up to 1 year of age, Gadovist will only be used in these patients after careful consideration by the doctor.

Other medicines and Gadovist

Tell your doctor if you are taking or have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Pregnancy

You must tell your doctor if you think you are, or might become, pregnant as Gadovist should not be used during pregnancy unless strictly necessary.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Your doctor will discuss whether you should continue or interrupt breast-feeding for a period of 24 hours after you receive Gadovist.

Gadovist contains sodium

This medicinal product contains less than 23 mg sodium per dose (based on the average amount given to a 70 kg person), i.e. essentially 'sodium-free'.

3. HOW GADOVIST WILL BE GIVEN

Gadovist is injected into your vein using a small needle by a healthcare professional. Your MRI examination can start immediately.

After the injection you will be observed for at least 30 minutes.

The usual dose

The actual dose that is right for you will depend on your body weight and on the region being examined by MRI:

In adults a single injection of 0.1 millilitre Gadovist per kg body weight is recommended (this means for a person weighing 70 kg the dose would be 7 millilitre), however a further injection of up to 0.2 millilitre per kg body weight within 30 minutes of the first injection may be given. A total amount of 0.3 millilitre Gadovist per kg body weight may be given at maximum (this means for a person weighing 70 kg the dose would be 21 millilitre) for imaging of the central nervous system (CNS) and CE-MRA. A dose of 0.075 millilitre Gadovist per kg body weight may be given at minimum (this means for a person weighing 70 kg the dose would be 5.25 millilitre) for the CNS.

Further information regarding the administration and handling of Gadovist is given at the end of the leaflet.

Dosage in special patient groups

The use of Gadovist is not recommended in patients with severe kidney problems and patients who have recently had, or soon expect to have, a liver transplant. However if use is required you should only receive one dose of Gadovist during a scan and you should not receive a second injection for at least 7 days.

Neonates, infants, children and adolescents

In children of all ages (including term newborn infants) a single dose of 0.1 millilitre Gadovist per kg body weight is recommended for all examinations (see section 1).

As kidney function is immature in babies up to 4 weeks of age and infants up to 1 year of age, Gadovist will only be used in these patients after careful consideration by the doctor. Neonates and infants should only receive one dose of Gadovist during a scan and should not receive a second injection for at least 7 days.

Elderly

It is not necessary to adjust your dose if you are 65 years of age or older but you may have a blood test to check how well your kidneys are working.

If you receive more Gadovist than you should

Overdosing is unlikely. If it does happen, the doctor will treat any symptoms and may use kidney dialysis to remove Gadovist from your body.

There is no evidence to suggest that this will prevent the development of nephrogenic systemic fibrosis (NSF; see section 4) and it should not be used as treatment for the condition. In some cases your heart will be checked.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The **most serious side effects** (which have been fatal or life-threatening in some cases) are:

- heart stops beating (cardiac arrest) and severe allergy-like (anaphylactoid) reactions (including stop of breathing and shock).
- In addition, for the **following side effects, life-threatening or fatal outcomes** have been observed in some cases:
- shortness of breath (dyspnoea), loss of consciousness, severe allergy-like reaction, severe decrease of blood pressure may lead to collapse, stop of breathing, fluid in the lungs, swelling of mouth and throat and low blood pressure.

In rare cases:

- **allergy-like reactions** (hypersensitivity and anaphylaxis) may occur, including severe reactions (shock) that may need immediate medical intervention.

If you notice:

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

tell the MRI department staff immediately. These 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 you have received Gadovist, have been observed in rare cases. If this should happen to you, tell your doctor or radiologist immediately.

The **most frequently observed side effects** (may affect 5 or more in 1,000 people) are:

- headache, feeling sick (nausea) and dizziness. Most of the side effects are mild to moderate.

Possible side effects which have been observed in **clinical trials** before the approval of Gadovist are listed below by how likely they are.

Common (may affect up to 1 in 10 people)

- headache
- feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people)

- allergy-like reaction, e.g.

- low blood pressure
- hives
- swelling of the face
- swelling (oedema) of the eyelid
- flushing

The frequency of the following allergy-like reactions is not known:

- severe allergy-like reaction (anaphylactoid shock)
- severe decrease of blood pressure may lead to collapse (shock)

► breathing stops

► fluid in the lungs

► breathing difficulties (bronchospasm)

► blueness of the lips

► swelling of the mouth and throat

► swelling of the throat

► increased blood pressure

► chest pain

► swelling of the face, throat, mouth, lips and/or tongue (angioedema)

► conjunctivitis

► increased sweating

► cough

► sneezing

► burning sensation

► pale skin (pallor)

► dizziness, disturbed sense of taste, numbness and tingling

► shortness of breath (dyspnoea)

► vomiting

► redness of the skin (erythema)

► itching (pruritus including generalized pruritus)

► rash (including generalized rash, small flat red spots [macular rash], small, raised, circumscribed lesions [papular rash] and itchy rash [pruritic rash])

► various kinds of injection site reactions (e.g. leakage into the surrounding tissue, burning, coldness, warmth, reddening, rash, pain or bruising)

► feeling hot

Rare (may affect up to 1 in 1,000 people)

► fainting

► convulsion

► disturbed sense of smell

► rapid heart beat

► palpitations

► dry mouth

► generally feeling unwell (malaise)

► feeling cold

Additional side effects which have been reported after the approval of Gadovist with unknown frequency (frequency cannot be estimated from the available data):

- Heart stops beating (cardiac arrest)

- There have been reports of nephrogenic systemic fibrosis - NSF (which causes hardening of the skin and may affect also soft tissue and internal organs).

Variations in blood tests of the kidney function (e.g. increase of serum creatinine) have been observed after administration of Gadovist.

Reporting of side effects

If you get any side effects talk to your doctor or radiologist. This includes any side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

To report any side effect(s):

Saudi Arabia

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>

Other Countries:

Please contact the relevant competent authority

5. HOW TO STORE GADOVIST

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Chemical, physical and microbiological in-use stability has been demonstrated for 24 hours at 20-25°C. From a microbiological point of view, the product should be used immediately after opening.

This medicinal product is a clear, colourless to pale yellow solution. Do not use this medicine if you notice severe discolouration or the presence of particulate matter or if the container appears defective.

Medicines should not be disposed of via wastewater or household waste. The healthcare professional will dispose of this medicine when no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Gadovist contains

The **active substance** is gadobutrol.

1 ml of solution for injection contains 604.72 mg gadobutrol (equivalent to 1 mmol gadobutrol containing 157.25 mg gadolinium).

1 prefilled syringe with 7.5 ml contains 4535.4 mg gadobutrol.

The **other ingredients** are calcobutrol sodium (see end of section 2), trometamol, hydrochloric acid 1N and water for injections.

What Gadovist looks like and contents of the pack

Gadovist is a clear, colourless to pale yellow solution for injection.</p



Gadovist®

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Bayer

