CONSUMER INFORMATION

MAGNEVIST®
gadopentetate dimeglumine injection

For Intravenous Use

For Professional Use Only

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MAGNEVIST. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MAGNEVIST is a contrast medium for magnetic resonance imaging (MRI) of the head, neck and spine.

MRI is a form of medical imaging that uses a complex system of magnets and radiowaves to obtain pictures of normal and abnormal tissues.

What it does:

MAGNEVIST helps tissues viewed by MRI appear brighter to make it easier for the healthcare professional to see any potential abnormalities.

When it should not be used:

Gadolinium-based contrast agents (such as MAGNEVIST) increase the risk of a rare disease called Nephrogenic Systemic Fibrosis (NSF) in patients with kidney disease. MAGNEVIST should not be used in:

- Patients with chronic, severe kidney disease
- Patients with acute kidney injury
- New-borns up to 4 weeks of age due to their developing kidneys

If you are hypersensitive (experience allergy-like reactions) to gadopentetate dimeglumine or to any of the other ingredients of MAGNEVIST (see below)

What the medicinal ingredient is:

gadopentetate dimeglumine

What the important nonmedicinal ingredients are:

meglumine, and diethylenetriamine pentaacetic acid

What dosage forms it comes in:

MAGNEVIST is a ready-to-use solution (corresponding to 0.5 mmol/mL) for rapid injection into a vein.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Gadolinium-based contrast agents (such as MAGNEVIST) increase the risk of a rare disease called Nephrogenic Systemic Fibrosis (NSF) in patients with kidney disease. MAGNEVIST should not be used in:

- Patients with chronic, severe kidney disease
- Patients with acute kidney injury
- New-borns up to 4 weeks of age due to their developing kidneys

Patients with mild to moderate kidney disease should only be given MAGNEVIST after a careful assessment by your physician.

MAGNEVIST should be used with caution in infants less than 1 year of age.

Your doctor will monitor your health before and after administration of MAGNEVIST if you are considered to be at risk for developing NSF (for details see Nephrogenic Systemic Fibrosis).

BEFORE you are given MAGNEVIST talk to your doctor if any of the following situations apply to you. The doctor will decide whether the intended examination is possible or not:

- You have or have had a previous reaction to contrast media
- You suffer or have suffered from an allergy (eg, hay fever, hives) or asthma.
- You have very poor kidney function.
- You have recently had, or soon expect to have, a liver transplant.
- You have epilepsy or suffer from brain conditions with seizures.
- You are pregnant or could be pregnant (even if you are not sure), since MAGNEVIST should not be used under such circumstances unless it is considered absolutely necessary.
- You suffer from heart or blood circulation problems. This is because in the rare event that you do have an allergic reaction, it is more likely to be serious or fatal.
- You have sickle cell anemia, hemolytic conditions (destruction of red blood cells), or related blood disorders of hemoglobin in the blood (hemoglobinopathies).

- Heart problems, breathing difficulties, or skin reactions may occur with the use of MAGNEVIST. Severe reactions may occur. Most of these reactions occur within half an hour of administration. Therefore, your attending healthcare professional may observe you in this period. Delayed reactions may occur hours or even days later.

MAGNEVIST may increase or decrease blood pressure, so caution must be used when driving or operating machinery.

Accumulation of Gadolinium in the Brain

Recent information shows that gadolinium (as in **MAGNEVIST**) 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

Kidney Impairment

Before you receive MAGNEVIST, your healthcare professional will check how well your kidneys are working. Patients with severe kidney disease should not be given MAGNEVIST (See WARNINGS AND PRECAUTIONS – Serious Warnings and Precautions). Patients with mild to moderate kidney disease should only be given MAGNEVIST after a careful assessment by your physician. Your doctor may decide to take a blood test to check this before making the decision to use MAGNEVIST.

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

MAGNEVIST can be removed from the body by dialysis. If you are already undergoing regular dialysis, your healthcare professional will decide if you should receive dialysis after you have been given MAGNEVIST.

Breastfeeding

MAGNEVIST is excreted in human breast milk. Discuss with your doctor.

Nephrogenic Systemic Fibrosis

There have been postmarket reports of a rare disease called Nephrogenic Systemic Fibrosis (NSF) following gadolinium-based contrast agent (GBCA) use.

NSF is a rare condition which has only been observed so far in patients with severe kidney disease. At present, there is no evidence that other patient groups are at risk of developing the condition. Due to NSF, the skin becomes thickened, coarse, and hard, which sometimes makes bending of the joints difficult. NSF may spread to other organs and even cause death.

Patients with severe kidney disease should avoid the use of MAGNEVIST unless the health care professional believes the possible benefits outweigh the potential risks. Those who have already had an MR imaging procedure and who have any of the following symptoms should seek medical attention as soon as possible:

- Swelling, hardening, and tightening of the skin
- Reddened or darkened patches on the skin
- Burning or itching of the skin
- Yellow spots on the whites of the eyes
- Stiffness in the joints, problems moving or straightening arms, hands, legs, or feet
- Pain deep in the hip bone or ribs
- Weakness of the muscles

Your healthcare professional will monitor your health after administering MAGNEVIST, if you are considered to be at risk for developing NSF.

INTERACTIONS WITH THIS MEDICATION

Drug interaction studies have not been done for MAGNEVIST.

Interference with Diagnostic Tests:

Before you have any blood tests, tell your healthcare professional you have been given MAGNEVIST. This is because some tests for iron levels in the blood may be affected for up to 24 hours after MAGNEVIST has been given.

Tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

PROPER USE OF THIS MEDICATION

Usual dose:

MAGNEVIST is injected by a healthcare professional via a needle or catheter into a vein. The recommended dose of MAGNEVIST is 0.2 millilitres per kg body weight. The actual dosage (volume) of MAGNEVIST that is right for you will depend on your body weight.

If you receive a bolus injection of MAGNEVIST (a large dose quickly) you may notice a temporary sweet taste in your mouth.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Common side effects observed in clinical trials (between 1 and 10 in every 100 patients are likely to get these):

- Headache (in some cases severe)
- Injection site discomfort

- Nausea (feeling sick)
- Pain (back, ear, eye, teeth)
- Hypersensitivity (allergic-like reactions) such as rash, hives, and swelling of the skin and mucous membranes (eg, mouth, throat, lips)
- Dizziness
- Vomiting
- Paresthesia ("pins and needles")

The most serious side effects in patients receiving MAGNEVIST are Nephrogenic Systemic Fibrosis (NSF) and anaphylactoid reactions (allergy-like reactions) including severe reactions such as shock.

In rare cases (1 to 10 in 10 000 patients), serious **allergy-like reactions** may occur including severe reactions such as 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, stopped breathing, itching, runny nose, hives, throat tightness, voice box spasm, blue lips, or lose consciousness, **tell your healthcare professional 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 reactions hours to several days after the administration of MAGNEVIST, have been observed in rare cases. If this should happen to you tell your healthcare professional.

The following side effects have been life-threatening or fatal in some cases:

- Fainting
- Heart rhythm disturbances: slow heartbeat, fast heartbeat, irregular heartbeat, or chest pain
- Heart stopping (cardiac arrest)
- Fits or seizures
- Unresponsiveness
- Coma
- Fluid in the lungs
- Nephrogenic systemic fibrosis (NSF)
- Acute kidney failure

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Serious allergy-like reactions, sometimes fatal, with symptoms such as swelling of the mouth and throat, difficulty in breathing, rash.		✓	

This is not a complete list of side effects. For any unexpected effects while taking MAGNEVIST, contact your doctor or pharmacist.

HOW TO STORE IT

MAGNEVIST should be stored at temperatures between 15°C to 30°C. MAGNEVIST is sensitive to light. Keep the container in the outer carton in order to protect from light.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program:

You can report any suspected adverse reactions associated with the use of heath products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or Canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: http://www.bayer.ca or by contacting the manufacturer at the above-mentioned phone number and email address

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