

MAGNEVIST[®] (MAG·ne·vist)

dimeglumine gadopentetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Magnevist against the benefits they expect it will have for you.

If you have any concerns about using this diagnostic agent, ask your doctor.

Keep this leaflet.

You may need to read it again.

WHAT MAGNEVIST IS USED FOR

Magnevist is used at the same time as magnetic resonance imaging (MRI) to aid in the detection of abnormalities in the brain, spinal cord, neck, chest, abdomen, pelvis, bones and muscles in adults; and in the brain and spinal cord in children and babies.

MRI is a form of medical diagnostic imaging that forms pictures after detecting water molecules in normal and abnormal tissues. This is done using a complex system of magnets and radiowaves. Magnevist is a liquid that alters the way in which the MRI machine detects certain tissues within the body. Magnevist often makes the pictures clearer and the diagnosis more

conclusive. It shows things that may not have been visible using MRI alone.

Ask your doctor/radiologist if you have any questions about why Magnevist is being used in you.

Your doctor may be using it for another reason.

Should you have any questions on the use of Magnevist in your MRI examination, these should immediately be discussed with the staff at the MRI unit performing the examination.

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

BEFORE YOU ARE GIVEN MAGNEVIST

When you must not be given it

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

- dimeglumine gadopentetate, the active ingredient in Magnevist
- 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 Magnevist if you have

severe disturbances of kidney function.

If you are not sure whether you should be given Magnevist, talk to your doctor/radiologist.

Before you are given it

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

Tell your doctor if you:

- carry a cardiac pacemaker or whether there are any ferromagnetic implants in your body
- had a previous reaction to contrast media
- are pregnant or intend to become pregnant
- are breastfeeding
- suffer from allergy (e.g. hay fever, hives) or bronchial asthma
- have a serious heart condition
- suffer from brain conditions with seizures
- have renal disease or insufficiency

If you suffer from any of these, your doctor will decide whether the intended examination is possible or not.

You should also fast for the last 2 hours prior to the examination but you may drink as usual. Further directions will be given by your doctor.

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

Taking other medicines

Tell your doctor 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 Magnevist may interfere with each other.

These include:

- beta-blockers (medicines used to treat high blood pressure or other heart conditions) since they may affect the way Magnevist works in your body.

Your doctor will advise you how to take these medicines before the examination.

HOW MAGNEVIST IS GIVEN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions given, ask your doctor for help.

The radiologist (MRI specialist doctor) will advise the use of Magnevist if he/she feels that it is likely to assist the MRI examination in finding out more about your condition.

How much is given

The actual dosage of Magnevist that is right for you will be worked out by the radiologist and will depend on the region of your body to be examined.

Normally only a single dose of about 15 to 20 mL of Magnevist will be required.

How it is given

Magnevist is injected by a doctor via a small needle into a vein, usually in the back of your hand or in front of your elbow.

When it is given

Magnevist will be administered immediately before your MRI examination.

If you are given too much (overdose)

The method of administration means that overdosage is unlikely. However, if it does occur it is possible to remove Magnevist from the body by means of a blood-cleansing procedure (dialysis).

If in doubt it is advisable 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 Magnevist. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

SIDE EFFECTS

Tell your doctor as soon as possible if you do not feel well while you are being given Magnevist.

All contrast media 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:

- dizziness
- headache
- strange taste
- nausea or vomiting

- local reaction around the injection site namely, pain, coldness, warmth, or a burning sensation

These are the more common side effects of Magnevist. Mostly these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- conjunctivitis, watery eyes, disturbed vision, smell, hearing or speech
- ear or eye pain, ringing in the ears, pins and needles or a burning sensation
- agitation, confusion, or disorientation
- muscle convulsion or tremor
- drowsiness, dizziness or light-headedness
- flushing, red or itchy skin; rash, or hives
- blue lips and skin
- uncomfortable or irritated throat with swelling, or pain or a sensation of tightness
- coughing, sneezing, wheezing, hayfever, breathlessness, difficulty breathing, or a change in breathing rate
- back pain or sore joints
- increased serum iron, bilirubin or liver enzymes
- chest pain or an abnormal, fast or slow heart beat
- low or high blood pressure
- stomach pain or discomfort, diarrhoea, salivation, toothache, dry or sore mouth
- uncontrollable passing of urine, or feel an urgent need to pass urine
- an area of swelling with pain, with or without skin redness
- chills, fever, generally feeling unwell, tired or thirsty
- swollen face
- discolouration and thickening of the skin (may feel “woody” and resemble an orange-peel texture), that may be painful and result in reduced joint mobility

(nephrogenic systemic fibrosis)

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (signs of shock)
- heart symptoms including a racing heart.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor, radiologist or MRI centre personnel if you notice anything that is making you feel unwell.

AFTER USING MAGNEVIST

Storage

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

PRODUCT DESCRIPTION

What it looks like

Magnevist is supplied as a sterile solution in bottles containing 10 mL and 30 mL and in pre-filled syringes containing 10 mL and 15 mL.

Ingredients

Active ingredients:

- Magnevist – contains 469 mg dimeglumine gadopentetate per mL

Inactive ingredients:

- meglumine
- meglumine pentetate, DTPA
- water for injections

Supplier

Made in Germany for:

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

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

Australian registration number

10 mL vial – AUST R 10697
30 mL vial – AUST R 59542
10 mL pre-filled syringe – AUST R 54671
15 mL pre-filled syringe – AUST R 54670
15 mL vial - AUST R 48494
20 mL vial - AUST R 48495
20 mL Pre-filled syringe - AUST R – 54669
100 mL bottle – AUST R 90883

Date of preparation

September 2011

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

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