

Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

## **Package Leaflet: Information for the user**

### **MAGNEVIST® 2 mmol/l solution for injection dimeglumine gadopentetate**

**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 the doctor giving you Magnevist 2 mmol/l (the radiologist) or the hospital/MRI-centre staff.
- If you get any side effects, talk to your doctor, radiologist or the hospital/MRI-centre staff. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

## **1. What Magnevist 2 mmol/l is and what it is used for**

Magnevist 2 mmol/l is used together with a technique called Magnetic Resonance Imaging (MRI) to create artificial contrast or enhancement to help make an MRI scan of your joints clearer.

MRI is a modern scanning technique which produces very high quality pictures of various parts of your body without using X-rays. The use of MRI can provide a quick, early and accurate diagnosis.

The scanner uses a strong magnetic field and radiowaves to measure the magnetic properties of body tissues. Using a computer, this information is converted into a black and white picture which can help your doctor see and investigate the differences between normal and abnormal tissue.

Sometimes MRI is used in areas where it cannot produce a clear black and white picture. This is when Magnevist 2 mmol/l is used. Magnevist 2 mmol/l produces a clearer image and allows the doctor to see the area of interest better. Sometimes several scans will be taken before Magnevist 2 mmol/l is injected and then further scans taken after the injection.

This medicine is for diagnostic use only.

## 2. What you need to know before you are given Magnevist 2 mmol/l

### Do not use Magnevist 2 mmol/l:

- If you are allergic to dimeglumine gadopentetate or any of the other ingredients of this medicine (listed in section 6)
- If you have a **heart pacemaker** or if there are any implants or clips containing iron inside your body. (This is not because of an interaction with Magnevist 2 mmol/l but because if you have any of these, you should not be placed in a strong magnetic field).

### Warnings and precautions

Talk to your radiologist or MRI-centre staff before receiving Magnevist 2 mmol/l  
Your doctor will need to take special care when giving you Magnevist 2 mmol/l if:

- you have a **history of allergy** (e.g. hay fever, hives), **asthma**, or have had a reaction to another type of contrast media. This is because you may be more likely to have an allergic reaction. If you have had any of these in the past, tell the radiologist or MRI-centre staff.
- you have an **infected joint**.

Before you receive Magnevist 2 mmol/l, you must tell the radiographer or MRI-centre staff if any of these apply to you.

- Accumulation in the body

Magnevist 2 mmol/l works because it contains a metal called gadolinium. Studies have shown that small amounts of gadolinium can remain in the body, including the brain.

This has not been seen following the small amounts given with injections into the joint.

### Other medicines and Magnevist 2 mmol/l

Tell the radiologist or MRI-centre staff if you are taking, have recently taken or might take any other medicines.

### Pregnancy and breast-feeding

Gadopentetic acid can cross the placenta. It is not known whether it affects the baby. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the MRI-centre staff for advice before receiving this medicine. A very small amount of Magnevist enters the breast milk, but this isn't likely to cause any harm.

### Driving and using machines

The volume of Magnevist 2 mmol/l injected into your joint may limit your movement. Do not drive if your movement is affected.

### Magnevist 2 mmol/l contains sodium

This medicine contains 67.6 mg sodium (main component of cooking/table salt) per pre-filled syringe. This is equivalent to 3.38 % of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How you will be given Magnevist 2 mmol/l

You will be asked to sit or lie down and Magnevist 2 mmol/l will be injected into the joint which is being investigated. Scanning may start immediately after the Magnevist 2 mmol/l injection. The MRI staff will observe you for at least 30 minutes after the injection just in case you have any side effects.

Adults:

The dose of Magnevist 2 mmol/l varies depending on which joint is investigated. For most joints, 20 ml is used, but up to 50 ml may be used for the knee joint. The doctor will decide how much Magnevist 2 mmol/l is needed for your investigation.

Children:

Magnevist 2 mmol/l is not recommended for use in children.

#### **If you receive more Magnevist 2 mmol/l than you should**

Overdosing is unlikely. If this does occur no serious ill-effects are expected.

If you have any further questions on the use of this medicine, ask the MRI-centre staff.

### 4. Possible side effects

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

Side effects you may get after being given a contrast medium like Magnevist 2 mmol/l are usually mild to moderate.

If you notice:

- itching of the skin, rash, wheals on the skin (urticaria)
- difficulty breathing, gagging, feeling of suffocation
- swelling of the face, neck or body
- itchy or watery eyes, tickling in the throat or nose, hoarseness, coughing or sneezing
- headache, dizziness, feeling faint
- feeling particularly hot or cold, sweating
- paleness or reddening of the skin
- chest pain, cramp, tremor
- feeling sick

**Tell the radiologist or MRI staff immediately** as these may be the first signs of allergic reaction or shock. Your investigation will need to be stopped and you may need further treatment.

Apart from the symptoms listed above, these are the possible side effects of Magnevist 2 mmol/l, starting with the more common ones:

**Common**      **may affect up to 1 in 10 people**

sensations or reactions at the injection site (such as pain, joint pressure and temporary discomfort)

**Uncommon**   **may affect up to 1 in 100 people**

feeling sick  
dizziness  
headache

**Rare may affect up to 1 in 1,000 people**

being sick  
slowed heartbeat; lowered blood pressure; fainting  
allergic-type skin reactions including itching, redness, wheals on the skin

Delayed reactions can occur (after hours or days), if you are concerned you should contact your doctor.

**Reporting of side effects**

If you get any side effects, talk to your radiologist or MRI-centre staff. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Magnevist 2 mmol/l

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

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

## 6. Contents of the pack and other information

### What Magnevist 2 mmol/l contains

- The active substance is dimeglumine gadopentetate.  
1 ml Magnevist 2 mmol/l contains 1.876 mg of the dimeglumine salt of gadopentetic acid.
- The other ingredients are meglumine, pentetic acid, sodium chloride and water for injections.

### What Magnevist 2 mmol/l looks like and contents of the pack

Magnevist 2 mmol/l is a clear, colourless to pale yellow or brownish-yellow solution for injection.

Magnevist 2 mmol/l is available in 20 ml pre-filled syringes.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Bayer plc  
400 South Oak Way  
Reading  
RG2 6AD

Manufacturer:

Bayer AG  
Müllerstraße 178  
13353 Berlin  
Germany

**This leaflet was last revised in April 2024.**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

<b>Product name</b>	<b>Reference number</b>
MAGNEVIST® 2 mmol/l solution for injection	00010/0544

This is a service provided by the Royal National Institute of the Blind.

Magnevist® is a trademark of the Bayer Group.