Magnevist® (gadopentetic acid, dimeglumine salt) 2mmol/l solution for injection

Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Glass pre-filled syringes containing 20ml of gadopentetic acid, dimeglumine salt (1.876 mg/ml). **Indications:** Contrast enhancement in direct magnetic resonance arthrography. For diagnostic use by intraarticular administration only. Use only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI) and when another authorised product cannot be used. **Posology and method of administration (at 0.2 to 1.5 Tesla):** Observe usual precautions for MRI (e.g. exclusion of cardiac pacemakers and other ferro-magnetic objects including vascular clips etc). Give dose via intraarticular injection under strict aseptic technique and with patient lying or sitting. Contrast-enhanced MRI can start immediately afterwards. Observe patient for at least 30 minutes after administration. Use the lowest dose that provides sufficient enhancement for diagnostic purposes. ***Adults:*** In general, for all joints up to 20ml (knee joint up to 50ml) is sufficient. Inject a volume leading to slight distension of the joint capsule, until discrete resistance is felt and/or the patient feels a mild pressure. ***Paediatric population:*** Safety and efficacy of Magnevist 2mmol/l in children aged up to 18 years has not yet been established. No data are available. Not recommended until further data become available. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and precautions:** Use strict aseptic technique to prevent infection. Use fluoroscopic control to ensure proper needle placement and prevent extracapsular injection. Do not exert undue pressure during injection and avoid infected joints. ***Hypersensitivity:*** Severe systemic hypersensitivity reactions cannot be excluded. Mild angioedema, conjunctivitis, coughing, pruritus, rhinitis, sneezing and urticaria may be first signs of incipient state of shock, irrespective of amount administered or method of administration. Delayed reactions (after hours or days) may occur. Post-procedure observation is recommended. Appropriate drugs and instruments must be readily available for treatment of hypersensitivity reactions. The risk of hypersensitivity reaction is higher in patients with previous reaction to contrast media, a history of bronchial asthma or allergic disorders. In patients with an allergic disposition, carefully evaluate risk-benefit ratio. After intravenous administration of gadopentetic acid, dimeglumine salt, gadolinium can be retained in the brain and in other body tissues (bones, liver, kidneys, skin) and can cause dose-dependent increases in T1-weighted signal intensity in the brain, particularly in the dentate nucleus, globus pallidus, and thalamus. Clinical consequences are unknown. Retention of gadolinium in the brain has not been identified for intra-articular administration. The possible diagnostic advantages of using gadopentetic acid, dimeglumine salt in patients requiring repeated scans should be weighed against the potential for deposition of gadolinium in the brain and other tissues. Magnevist 2mmol/l contains sodium (SmPC section 4.4). **Interactions:** Do not mix Magnevist 2mmol/l with iodinated contrast media since this will reduce efficacy. **Pregnancy and lactation:** No clinical data on exposed pregnancies are available. Exercise caution with use in pregnant women. No data exist concerning intraarticular administration in lactating women. After intravascular use a max. of 0.04% of IV administered dose enters breast milk and is considered unlikely to cause harm to infants. **Effects on ability to drive and use machines:** No effects of Magnevist 2mmol/l on driving ability or use of machinery expected but the joint effusion may affect driving due to a limited joint mobility. **Undesirable effects:** Frequencies are from clinical trial data. Undesirable effects listed here were classified by investigators as drug-related. Adverse reactions are usually of mild to moderate intensity. ***Common*:** Injection site pain/pressure sensation (joint). ***Serious: cf. CI/W&P - in addition: Immune system disorders/hypersensitivity/allergic reaction:*** Systemic hypersensitivity may occur rarely as skin reactions. Severe hypersensitivity reactions cannot be excluded. ***General disorders and administration site conditions:*** Severe pain may often result from undue use of pressure or injection of large volumes. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** No signs of intoxication secondary to overdose have been reported. **Legal Category:** POM **Package Quantities and Basic NHS Costs:** 1 x 20ml pre-filled syringe £29.05 **MA Number:** PL 00010/0544 **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, UK. **Telephone**: 0118 206 3000 **Date of preparation:** September 2020.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Bayer plc; Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com