Gadovist® (gadobutrol)

Gadovist® 1.0 mmol/ml solution for injection (gadobutrol) and Gadovist® 1.0 mmol/ml solution for injection pre-filled syringe/cartridge (gadobutrol) Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)
Presentation: Glass vials containing 15ml, or glass prefilled syringes containing 5ml, 7.5ml or 10ml, of gadobutrol 1.0 mmol/ml solution for injection (604.72 mg gadobutrol/ml). **Indications:** ***Adults and children of all ages (including term neonates):*** Contrast enhancement in cranial and spinal MRI; MRI of liver and kidneys if suspicion or evidence of focal lesions; MRI of pathologies of the whole body and in magnetic resonance angiography (CE-MRA). Use only when diagnostic information is essential and not available with unenhanced MRI. **Posology and method of administration:** Gadovist should only be administered by healthcare professionals experienced in the field of clinical MRI practice. This medicinal product is for intravenous administration only. Give required dose intravenously as bolus injection. Patient should be recumbent during administration. MRI can start immediately after injection. Optimal signal enhancement usually occurs during arterial first pass for CE-MRA and within 15 minutes of injection for CNS indications. Particularly suitable for T1-weighted scanning sequences. Observe patient for at least 30 minutes after administration. Intended for single use only. Contrast medium not used in one examination must be discarded. Visually inspect before use; do not use in case of severe discolouration, occurrence of particulate matter or defective container. *Vials*: draw up into syringe immediately before use; never pierce rubber stopper more than once. *Pre-filled syringe:* prepare immediately before administration. Use the lowest dose that provides sufficient enhancement for diagnostic purposes. The dose should be calculated based on the patient's body weight, and should not exceed the recommended dose per kg of body weight detailed below. **CNS indications:** ***Adults*****:** 0.1mmol/kg body weight (BW) (equivalent to 0.1ml/kg BW). A further injection of 0.2ml/kg BW may be given within 30 minutes of first injection. **Whole Body MRI (except MRA):** ***Adults:*** 0.1 ml/kg BW. **CE-MRA:** ***Adults*****:** Imaging of 1 field of view (FOV): 7.5ml for BW below 75 kg, 10ml for BW of 75 kg and higher (corresponding to 0.1-0.15 mmol/kg BW). Imaging of >1 FOV: 15ml for BW below 75 kg, 20ml for BW of 75 kg and higher (corresponding to 0.2-0.3 mmol/kg BW). ***Renal impairment:*** Only use in patients with severe renal impairment (GFR < 30ml/min/1.73m2), and in patients in perioperative liver transplantation period after careful risk/benefit assessment and if diagnostic information is essential and not available with non-contrast enhanced MRI. If it is necessary to use Gadovist, dose should not exceed 0.1 mmol/kg BW. Do not use more than one dose per scan. Do not repeat the dose for at least 7 days. ***Paediatric population:*** For children of all ages (including term neonates): 0.1mmol/kg BW (equivalent to 0.1ml/kg BW) for all indications. ***Neonates up to 4 weeks of age and infants up to 1 year of age:*** Due to immature renal function Gadovist should only be used in these patients after careful consideration at a dose not exceeding 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, Gadovist injections should not be repeated unless the interval between injections is at least 7 days. ***Elderly (65+ years):*** No dose adjustment necessary but exercise caution. **Contra-indications:** Hypersensitivity to ingredients. **Warnings and precautions:** If injecting into veins with a small lumen, adverse effects such as reddening or swelling may occur. As with other intravenous contrast agents, Gadovist can be associated with anaphylactoid/hypersensitivity or other idiosyncratic reactions, characterised by cardiovascular, respiratory or cutaneous manifestations ranging to severe reactions including shock. In general, patients with cardiovascular disease are more susceptible to serious or fatal outcomes of severe hypersensitivity reactions. Risk of hypersensitivity reactions may be higher in case of previous reaction to contrast media, history of bronchial asthma and allergic disorders. In patients with an allergic disposition, carefully evaluate the risk-benefit ratio. Most reactions occur within half an hour of administration. Medication for the treatment of hypersensitivity reactions as well as preparedness for the institution of emergency measures are necessary. In rare cases, delayed anaphylactoid reactions (after hours to days) have been observed. Prior to administration, it is recommended to screen all patients for renal dysfunction by laboratory testing. Nephrogenic systemic fibrosis (NSF) has been reported with some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30ml/min/1.73m2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. Only use in patients with severe renal impairment and those in the perioperative liver transplantation period after careful risk/benefit assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI. Haemodialysis shortly after Gadovist administration may be useful in removing Gadovist from the body. As renal clearance may be impaired in the elderly, it is particularly important to screen patients aged 65+ years for renal dysfunction. Use with caution in patients with a low seizure threshold. **Fertility, pregnancy and lactation:** Animal studies do not indicate impairment of fertility, but have shown reproductive toxicity at repeated high doses. Do not use during pregnancy unless the clinical condition of the woman requires the use of gadobutrol. Gadolinium containing contrast agents are excreted into breast milk in very small amounts. At clinical doses no effects on the infant are anticipated. **Undesirable effects:** Most undesirable effects are of mild to moderate intensity. ***Common:*** Nausea, headache. ***Uncommon:*** Hypersensitivity/anaphylactoid reaction* (e.g. anaphylactoid shock*, circulatory collapse*, respiratory arrest*, pulmonary oedema*, bronchospasm, cyanosis, oropharyngeal swelling*, laryngeal oedema, hypotension*, blood pressure increased, chest pain, urticaria, face oedema, angioedema, conjunctivitis, eyelid oedema, flushing, hyperhidrosis, cough, sneezing, burning sensation, pallor), dyspnoea*. ***Rare:*** Loss of consciousness*, convulsion. ***Not known:*** Cardiac arrest*, Nephrogenic systemic fibrosis (NSF) (isolated cases). Patients with an allergic disposition more frequently suffer from hypersensitivity reactions. Fluctuations of renal function parameters including increases of serum creatinine have been observed. *There have been reports of life threatening and/or fatal outcomes from this adverse drug reaction (ADR). Prescribers should consult the SmPC in relation to other side effects. **Overdose:** No signs of intoxication from an overdose have so far been reported during clinical use. In case of overdose, perform cardiovascular monitoring (including ECG) and control renal function as a measure of precaution. In patients with renal insufficiency, Gadovist can be removed by haemodialysis. After 3 haemodialysis sessions approx. 98% of agent is removed from the body. There is no evidence that haemodialysis is suitable for prevention of NSF. **Incompatibilities:** Do not mix Gadovist with other medicinal products. **Legal category:** POM **Basic NHS Price:** 1 x 15ml vial £101.26, 1 x 7.5ml pre-filled syringe £50.63, 5 x 5 ml pre-filled syringes £168.77, 5 x 10ml prefilled syringes £337.54. MA Numbers: PL 00010/0535 (vials), PL 00010/0536 (prefilled syringes) **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** February 2018.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Bayer plc.
Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com