Gadovist® (gadobutrol)

Gadovist® 1.0 mmol/ml solution for injection (gadobutrol) and Gadovist® 1.0 mmol/ml solution for injection prefilled 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 of or detectable 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 function impairment (GFR < 30ml/min/1.73m²). All patients in 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, conjunctivitis, erythema, flushing, hyperventilation 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 associated with 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 pre-filled syringes £337.54, MA Numbers: PL 00010/0536 (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.

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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