PRESCRIBING INFORMATION OMNISCAN™ (gadodiamide)

Indications and approvals may vary in different countries. Please refer to the local Summary of Product Characteristics [SPC] before prescribing. Further information available on request.

PRESENTATION Non-ionic, paramagnetic aqueous solution containing 287mg/ml gadodiamide (GdDTPA-BMA), equivalent to 0.5mmol/ml.

INDICATIONS Contrast medium for cranial and spinal magnetic resonance imaging (MRI) and for general MRI of the body after intravenous administration. The product provides contrast enhancement and facilitates visualisation of abnormal structures or lesions in various parts of the body including the CNS. For cardiac MRI, the product is indicated for the evaluation of coronary artery disease (CAD) by myocardial perfusion imaging MRI (stress/rest and late enhancement examination) for the detection and localization of coronary artery disease (CAD) and differentiation between areas of ischaemia and infarction in subjects with known or suspected CAD.

DOSAGE AND METHOD OF ADMINISTRATION Adults and children: Dosage varies depending on patient weight and type of examination. Angiography and the CAD indication have not been studied in children.

CONTRAINDICATIONS Gadodiamide is contraindicated in patients with severe renal impairment (GFR<30 ml/min/1.73m^2), and those who have had or are undergoing liver transplantation. OMNISCAN should not be used in patients known to have hypersensitivity to OMNISCAN or its constituents.

PRECAUTIONS, WARNINGS ETC. The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions or other idio¬syncratic reactions should always be considered, especially in those patients with a known clinical hypersensitivity or a history of asthma or other allergic respiratory disorders. A course of action should therefore be planned in advance, with necessary drugs and equipment available for immediate treatment should a serious reaction occur. Transitory changes in serum iron (within the normal range in the majority of cases) have been observed. OMNISCAN interferes with serum calcium measurements with some complexiometric methods. Such methods should not be used for 12-24 hours after administration. Elimination of OMNISCAN is prolonged in patients with impaired renal function. Due to lack of information on such patients the interval between repeated administration should be at least seven days. Severe renal impairment and liver transplant patients: There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of gadodiamide and some other gadolinium-containing contrast agents in patients with severe renal impairment (GFR <30ml/min/1.73m2) and those who have had or are undergoing liver transplantation. Therefore OMNISCAN should not be used in these populations. Cases of NSF have also been reported in patients with moderate renal impairment (GFR <60 ml/min/1.73m2) with gadodiamide. OMNISCAN should be used in these patients with caution. Haemodialysis shortly after OMNISCAN administration in patients currently receiving haemodialysis may be useful at removing OMNISCAN from the body. There is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis. Neonates and Infants: Due to immature kidney function in neonates and infants up to 1 year of age, OMNISCAN should only be used in these patients after careful consideration.

PREGNANCY AND LACTATION There is no experience of the use of OMNISCAN during pregnancy or lactation. The product should not be used in pregnancy unless essential. Breast feeding should be discontinued prior to administration and should not be re-commenced until at least 24 hours after OMNISCAN administration.

UNDESIRABLE EFFECTS The most commonly reported spontaneous adverse effects are hypersensitivity reactions, nausea and vomiting. In clinical trials common adverse reactions are headache, nausea, transient sensation of warmth, coolness, local pressure and pain at injection site. Less frequently reported are dizziness, paraesthesia, a perverted sensation of taste, allergy-like skin and mucous membrane reactions, hypersensitivity, flushing, vomiting, diarrhoea and pruritus. Rare reactions are anxiety, convulsions, tremor, somnolence, transient perverted sensation of smell, visual disturbances, dyspnoea, coughing, rash, urticaria, oedema including face swelling and angioneurotic oedema, arthralgia, acute renal failure, chest pain, fever, shivering. Reported with unknown frequency are anaphylactic/anaphylactoid reactions, tachycardia, sneezing, throat irritation, bronchospasm, respiratory distress and nephrogenic systemic fibrosis (NSF). Anaphylactoid reactions may occur irrespective of the dose. Late adverse reactions can occur hours to days after OMNISCAN administration.

OVERDOSE Clinical consequences of overdose have not been reported. Acute symptoms of toxicity are unlikely in patients with normal renal function. In patients with delayed elimination due to renal insufficiency and patients who have received excessive doses, contrast medium can be eliminated by haemodialysis.

INSTRUCTIONS FOR USE AND HANDLING Containers are intended for single use only, any unused portions must be discarded. The product in glass vials and polypropylene bottles should be drawn into the syringe immediately before use.

MARKETING AUTHORISATION HOLDER GE Healthcare AS, Nycoveien 1-2, Postboks 4220 Nydalen, NO-0401 Oslo, Norway.

CLASSIFICATION FOR SUPPLY Subject to medical prescription (POM).

UK MARKETING AUTHORISATION NUMBERS 00637/0015 (glass vials), 00637/0025 (polypropylene bottles), 00637/0030 (pre-filled syringes).

PRICE 20ml: £59.24.

DATE OF REVISION OF THE TEXT 23 October 2008

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, England HP7 9NA
www.gehealthcare.com

References:

1. Sadowski EA *et al.* Nephrogenic Systemic Fibrosis: Risk Factors and Incidence Estimation. Radiology 2007;243:148–57.
2. Omniscan SmPC 2008.