PRESCRIBING INFORMATION CLARISCAN™ – gadoteric acid
Please refer to full national Summary of Product Characteristics (SmPC) before prescribing.
Further information available on request.

PRESENTATION
Clariscan 0.5 mmol/mL solution for injection and solution for injection in pre-filled syringe, containing 279.32 mg/ml gadoteric acid (as gadoterate meglumine) equivalent to 0.5 mmol/mL.

INDICATIONS
For diagnostic use only. Clariscan should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI). Contrast agent for contrast enhancement in MRI for a better visualisation/delineation. Adult and paediatric population (0-18 years): lesions of the brain, spine, and surrounding tissues. Adults and children over 6 months Whole body MRI. Non-coronary angiography in adults only.

DOSAGE AND METHOD OF ADMINISTRATION
This medicinal product should only be administered by trained healthcare professionals with technical expertise in performing and interpreting gadolinium enhanced MRI. The lowest dose that provides sufficient enhancement for diagnostic purposes should be used. The dose should be calculated based on the patient's body weight, and should not exceed the recommended dose per kilogram of body weight detailed in this section. **MRI of brain and spine:** ***Adults:*** The recommended dose is 0.1 mmol/kg BW, i.e. 0.2 mL/kg BW. In patients with brain tumours, an additional dose of 0.2 mmol/kg BW, i.e. 0.4 mL/kg BW, may improve tumor characterisation and facilitate therapeutic decision making. ***Children (0-18 years):*** The recommended and maximum dose of Clariscan is 0.1 mmol/kg body weight. Do not use more than one dose during a scan. Careful consideration in neonates up to 4 weeks and infants up to 1 year of age. Lack of information on repeated administration, Clariscan injections should not be repeated before 7 days. **Whole body MRI (including lesions of the liver, kidneys, pancreas, pelvis, lungs, heart, breast, and musculoskeletal system):** ***Adults and children over 6 months:*** The recommended dose is 0.1 mmol/kg BW, i.e. 0.2 mL/kg BW. **Angiography:** ***Adults only:*** The recommended dose, IV injection is 0.1 mmol/kg BW, i.e. 0.2 mL/kg BW. **Impaired renal function:** The adult dose applies to patients with mild to moderate renal impairment (GFR ≥ 30 ml/min/1.73m^2). Clariscan should only be used in patients with severe renal impairment (GFR < 30 mL/min/1.73 m^2) and in patients 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. If it is necessary to use Clariscan the dose should not exceed 0.1 mmol/kg body weight. Clariscan injections should not be repeated before 7 days. **Impaired hepatic function:** The adult dose applies. Caution recommended, especially in perioperative liver transplantation period. **Elderly (aged 65 years and above):** No dosage adjustment, but exercise caution.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the full SmPC.

WARNINGS AND PRECAUTIONS
Appropriate facilities should be readily available for any complication, as well as for emergency treatment of severe reaction to the contrast agent (e.g. hypersensitivity, seizures). The usual precaution for MRI examination should be taken. Regarding any metallic object such as exclusion of patients with pacemakers, vascular clips, infusion pumps, nerve stimulators, cochlear implants, or suspected intracorporeal metallic foreign bodies, particularly in the eye. **Gadoteric acid must not be used intrathecally.** Serious, life-threatening and fatal cases, primarily with neurological reactions (e.g. coma, encephalopathy, seizures), have been reported with intrathecal use. For intravenous injection only. **Extravasation:** In the event of extravasation local intolerance reactions may be observed, necessitating short term local treatment. **Hypersensitivity reactions:** Hypersensitivity reactions can occur, including life-threatening, and may be either allergic or non-allergic. They can be either immediate (less than 60 minutes), or delayed (up to 7 days). Anaphylactic reactions can occur immediately and can be fatal. Symptoms of an existing asthma may be aggravated. Hypersensitivity reactions can be aggravated in patients on beta-blockers, particularly those with bronchial asthma. These patients may be refractory to standard treatment of hypersensitivity reactions with beta-agonists. Caution in patients with a history of allergy (e.g. fish and seafood allergy, hay fever, hives), sensitivity to contrast media and bronchial asthma and premedication with antihistamines and/or glucocorticoids may be considered. Appropriate support measures should be available.

Nephrogenic Systemic Fibrosis (NSF): Reports of ***NSF*** associated with use of some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30 mL/min/1.73 m^2). Incidence of acute renal failure is high in patients undergoing liver transplantation. Clariscan should only be used in patients with severe renal impairment and in patients 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. Prior to administration of Clariscan, it is recommended that all patients are screened for renal dysfunction. **CNS disorders:** Special precaution is necessary in patients with a low threshold for seizures. **Cardiovascular disease:** Clariscan should only be administered after careful benefit assessment. **Patient preparation:** Nausea and vomiting are known possible undesirable effects when using MRI contrast agents. The patient should therefore refrain from eating for 2 hours prior to the investigation.

UNDESIRABLE EFFECTS

NSF [see Warnings and Precautions]. **Clinical Studies Experience: Immune system disorders:** Uncommon: Hypersensitivity. Very rare: Anaphylactic reaction, anaphylactoid reaction. **Psychiatric disorders:** Rare: Anxiety. Very rare: Agitation. **Eye disorders:** Rare: eyelid oedema. Very rare: Conjunctivitis, ocular hyperaemia, vision blurred, lacrimation increased. **Nervous system disorders:** Uncommon: Headache, dysgeusia, dizziness, somnolence, paraesthesia (including burning sensation). Rare: Presyncope. Very rare: Coma, convulsion, syncope, parosmia, tremor. **Cardiac disorders:** Rare: Palpitations. Very rare: Cardiac arrest, bradycardia, tachycardia, arrhythmia. **Respiratory, thoracic and mediastinal disorders:** Rare: Sneezing. Very rare: Respiratory arrest, pulmonary oedema, bronchospasm, laryngospasm, pharyngeal oedema, dyspnoea, nasal congestion, cough, dry throat. **Gastrointestinal disorders:** Uncommon: Nausea, abdominal pain. Rare: Vomiting, diarrhoea, salivary hypersecretion. **Skin and subcutaneous system disorders:** Uncommon: Rash. Rare: Urticaria, pruritus hyperhidrosis. Very rare: Erythema, eczema, angioedema. Isolated cases of NSF have been reported with gadoteric acid, most of which were in patients co-administered other gadolinium-containing contrast agents. **Vascular disorders:** Uncommon: Hypotension, hypertension. Very rare: Vasodilatation, pallor. **Musculoskeletal and connective tissue disorders:** Very rare: Muscle cramps, muscular weakness, back pain. **General disorders and administration site conditions:** Uncommon: Feeling hot, feeling cold, asthenia, injection site reactions (pain, extravasation, discomfort, oedema, inflammation, coldness). Rare: Chest pain, chills. Very rare: Malaise, chest discomfort, face oedema, pyrexia, injection site necrosis (in case of extravasation), superficial phlebitis. See full SmPC for adverse reactions reported with other intravenous MRI contrast agents.

Post-marketing experience: The most commonly reported adverse reactions following administration are nausea, vomiting, pruritus and hypersensitivity reactions. The most frequently observed hypersensitivity reactions are localised, extended or generalised skin reactions which most often occur immediately (during the injection or within one hour after the start of injection) or sometimes delayed (one hour to several days after injection). Immediate reactions include one or more effects, which appear simultaneously or sequentially, which are most often cutaneous, respiratory, gastrointestinal, articular and/or cardiovascular reactions. Each sign may be a warning sign of a starting shock and go very rarely to death.

Adverse reaction in children: Safety of paediatric patients was considered in clinical trials and post marketing studies. As compared to adult, the safety profile of gadoteric acid did not show any specificity in children. Most of reactions are gastrointestinal symptoms or signs of hypersensitivity.

DRUG INTERACTIONS

No formal studies. No interactions with other medicinal products have been observed. Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists: These medicinal products induce decreased efficacy of cardiovascular compensation mechanisms of blood pressure. Contrast media may increase the incidence of hypersensitivity reactions in patients taking beta-blockers.

PREGNANCY AND LACTATION

Data on the use of gadolinium-based contrast agents including gadoteric acid in pregnant women is limited. Gadolinium can cross the placenta. It is unknown whether exposure to gadolinium is associated with adverse effects in the foetus. Clariscan should not be used during pregnancy unless the clinical condition of the woman requires use of gadoteric acid. **Nursing Mothers:** At clinical doses, no effects on the infant are anticipated due to the small amount excreted in milk and poor absorption from the gut. Continuing or discontinuing breast feeding for a period of 24 hours after administration, should be at the discretion of the doctor and lactating mother. **Fertility:** no clinical data.

SPECIAL POPULATIONS
Neonates and infants: Clariscan should only be used in neonates up to 4 weeks of age and infants up to 1 year age after careful consideration.
Elderly (aged 65 years and above): Patients should be screened due to age related decline in renal function.

OVERDOSE
Clariscan can be removed by haemodialysis. However, there is no evidence that haemodialysis is suitable for prevention of NSF.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES
No studies. Ambulant patients while driving vehicles or operating machinery should take into account that nausea may incidentally occur.

INSTRUCTIONS FOR USE AND HANDLING
For single use. The solution for injection should be inspected visually prior to use. Only clear solutions free of visible particles should be used. In neonates and infants the required dose should be administered by hand. The peel-off tracking label on the syringes/vials/bottles should be stuck onto the patient record. The dose used should also be recorded. See SmPC for full instructions.

MARKETING AUTHORISATION HOLDER
GE Healthcare AS, Nycoveien 1, 0485 OSLO, NORWAY

MARKETING AUTHORISATION NUMBER
PL 00637/0065 and PL 00637/0066

CLASSIFICATION FOR SUPPLY
Subject to medical prescription (POM)

DATE OF REVISION OF THE TEXT
Date of revision of text: (July 2025), based on SmPC dated (July 2025).

Cost (to be added by Marketing when used).
10x15ml: £666

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.
Adverse events should also be reported to GE HealthCare at gpv.drugsafety@gehealthcare.com.