PRESCRIBING INFORMATION

DOTAREM® 0.5 mmol/ml (Gadoteric acid) Solution for injection, vials and pre-filled syringe (PFS)
Please consult full Summary of Product Characteristics (SmPC) before using. The following is a summary:
ACTIVE INGREDIENT: Gadoteric acid, 279.32 mg/ml (equivalent to 0.5 mmol/ml). Osmolality: 1350 mOsm.kg^{-1}. Viscosity at 20°C: 3.2 mPa.s (2.0 mPa.s at 37°C), pH: 6.5 to 8.0. **THERAPEUTIC INDICATIONS:** Dotarem should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI). *Adults and paediatric population (0-18years)*. Contrast enhancement in Magnetic Resonance Imaging: ***Encephalic and spinal MRI:*** Detection of brain tumours, tumours of the spine and surrounding tissue, intervertebral disc prolapse, infectious diseases; ***Whole Body MRI:*** Including renal, cardiac, uterine, ovarian, breast, abdominal and osteo-articular pathology; ***Angiography*****:** Dotarem is not recommended for angiography in children under 18 years of age due to insufficient data on its efficacy and safety in this indication. **POSOLOGY AND METHOD OF ADMINISTRATION:** 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**.** The product is intended for IV administration only. Intravascular administration of contrast media should, if possible, be done with the patient lying down. After the administration, the patient should be kept under observation for at least half an hour, since experience shows that the majority of undesirable effects occur within this time. **Adults including the elderly:** *Encephalic and spinal MRI:* The recommended dose is 0.1mmol.kg^{-1}, i.e. 0.2ml.kg^{-1} to provide diagnostically adequate contrast. A further injection of 0.2mmol.kg^{-1}, i.e. 0.4ml.kg-1 within 30 minutes, may improve tumour characterisation and facilitate therapeutic decision making. *Whole body MRI and angiography:* The administration of 0.1mmol.kg^{-1}, i.e. 0.2ml.kg^{-1} is recommended to provide diagnostically adequate contrast. *Angiography:* In exceptional circumstances administration of a second consecutive injection of 0.1mmol.kg^{-1}, i.e 0.2ml.kg^{-1} may be justified. However, if the use of 2 consecutive doses of DOTAREM® is anticipated prior to commencing angiography, the use of 0.05 mmol.kg^{-1} (i.e. 0.1ml.kg^{-1}) for each dose may be of benefit, depending on the imaging equipment available. **Paediatric population (0-18 years):** *Brain and spinal MRI, whole body MRI*: the recommended and maximum dose of Dotarem is 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Due to immature renal function in neonates up to 4 weeks of age and infants up to 1 year of age, Dotarem should only be used in these patients after careful consideration, at a dose not exceeding 0.1 mmol/kg body weight, *Angiography:* The efficacy and safety of DOTAREM® in children under 18 years has not been established. **Patients with renal impairment:** The adult dose applies to patients with mild to moderate renal impairment (GFR > 30ml/min/1.73m^2). Nephrogenic systemic fibrosis (NSF) has been reported with gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30ml/min/1.73m^2). As there is a possibility that NSF may occur with DOTAREM®, it should therefore only be used in this group 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 DOTAREM®, the dose should not exceed 0.1 mmol.kg^{-1}. Because of the lack of information on repeated administration, DOTAREM® injections should not be repeated unless the interval between injections is at least 7 days Isolated cases of nephrogenic systemic fibrosis (NSF) have been reported with gadoteric acid most of which were in patients co-administered with other gadolinium-containing contrast agents. **Patients with hepatic impairment:** The adult dose applies to these patients. Caution is recommended especially in the perioperative liver transplantation period. **CONTRA-INDICATIONS:** Hypersensitivity to gadoteric acid, to meglumine or to any medicinal product containing gadolinium. **SPECIAL WARNINGS AND PRECAUTIONS OF USE:** Do not use by intrathecal route. Dotarem should be strictly administered via intravenous injection: Serious, life-threatening and fatal cases, primarily with neurological reactions (e.g. coma, encephalopathy, seizures), have been reported with intrathecal use. Extravasation may result in local intolerance reactions, requiring the usual local care. The usual precaution measures for MRI examination should be taken, such as exclusion of patients with pacemakers, ferromagnetic vascular clips, infusion pumps, nerve stimulators, cochlear implants, or suspected intracorporal metallic foreign bodies, particularly in the eye. **Hypersensitivity:** Hypersensitivity reactions can be either immediate (<60 minutes) or delayed (up to 7 days), allergic or non-allergic. Anaphylactic reactions occur immediately, can be fatal and are independent of dose. There is always a risk of hypersensitivity regardless of the dose injected. Patients with hypersensitivity

or previous reaction to contrast media are at increased risk of severe reaction. In these patients DOTAREM® should only be administered after careful consideration of the risk/benefit ratio. Hypersensitivity reactions may be aggravated in asthmatic patients or those taking beta-blockers. During the examination, supervision by a physician is necessary. If hypersensitivity occurs, administration of the contrast medium must be discontinued immediately, and appropriate specific therapy instituted. **Impaired renal function:** Prior to administration of DOTAREM®, it is recommended that all patients especially those above 65 years are screened for renal dysfunction by obtaining laboratory tests. Due to the risk of NSF in patients with acute or chronic severe renal impairment, administration in this group should be considered and performed as above. Haemodialysis shortly after administration may be useful in removing DOTAREM® from the body. However, there is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis. **CNS disorders**: Special precaution is necessary in patients with a low threshold for seizures. All equipment and drugs necessary to counter any convulsions must be readily available. **INTERACTIONS:** No interactions with other medicinal products have been observed. Formal drug interactions studies have not been carried out. **PREGNANCY AND LACTATION: Pregnancy: D**ata 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. Animal studies do not indicate direct or indirect harmful effects. Administration during pregnancy should be avoided unless absolutely necessary. **Lactation:** Gadolinium containing contrast agents are excreted into breast milk in very small amounts (see section 5.3 of the SmPC). 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 of DOTAREM®, should be at the discretion of the doctor and lactating mother. **UNDESIRABLE EFFECTS:** Side effects associated with use of gadoteric acid are usually mild to moderate in intensity and transient in nature. Injection site reactions, nausea and headache are the most frequently observed reactions, as well as feeling cold, hypotension, somnolence, dizziness, feeling hot, burning sensation, rash, asthenia, dysgeusia and hypertension are also most frequent. **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. Please consult the SmPC in relation to other side effects. **MARKETING AUTHORISATION HOLDER:** Guerbet B.P. 57400 F-95943 Roissy CdG Cedex France. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBERS:** PL 12308/0016 (vials); PL 12308/0017 (PFS). **LIST PRICE:** 10 x 5ml vials £272.50, 10 x 10ml vials £440.20, 10x 15ml PFS £569.10, 10 x 20ml PFS £666.50. **DATE OF REVISION OF TEXT:** 01-Jul-2024. PDOT-PI-DIGITAL-JULY2024_36

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Or Search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Guerbet Laboratories Ltd. Avon House, 435 Stratford Road, Shirley, Solihull, B90 4AA. Tel: 0121 733 8542 Fax: 0121 733 3120 Email: uk.info@guerbet.com