



Because Gd^{3+} can bite... Control it!



Contrast for Life, **DOTAREM[®]** Gadoteric acid by Choice

Dotarem[®] 0.5 mmol/mL, solution for injection in vials and pre-filled syringes: 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. - **QUALITATIVE AND QUANTITATIVE COMPOSITION PER 100 mL:** Gadoteric acid* (27.932 g) corresponding to DOTA (20.246 g) - Gadolinium oxide (9.062 g) - Excipients: Meglumine, water for injections (*Gadoteric acid: gadolinium complex of 1,4,7,10 tetraazacyclododecane-N,N',N'',N''' tetraacetic acid). **CLINICAL PARTICULARS: Therapeutic indications:** Magnetic Resonance Imaging for cerebral and spinal disease, diseases of the vertebral column, and the other whole-body pathologies (including angiography). **Posology and method of administration:** The recommended dose is 0.1 mmol/kg, ie 0.2 mL/kg in adults, children and infants. In angiography, depending on the results of the examination being performed, a second injection may be administered during the same session if necessary. In some exceptional cases, as the confirmation of isolated metastasis or the detection of leptomeningeal tumors, a second injection of 0.2 mmol/kg can be administered. The product must be administered by strict intravenous injection. **Contraindications:** History of hypersensitivity to gadolinium salts. Contraindications related to MRI: subjects with a pacemaker, subjects with a vascular clip. **Special warnings and special precautions for use:** Administer only by strict intravenous injection. Dotarem[®] must not be administered by subarachnoid (or epidural) injection. Caution is recommended for anaphylactic-like reactions, renal insufficiency and CNS disorders. There have been reports of Nephrogenic Systemic Fibrosis (NSF) associated with use of some gadolinium-containing contrast agents in patients with severe renal impairment (GFR < 30 mL/min/1.73 m²). As there is a possibility that NSF may occur with Dotarem[®], it should only be used in these patients after careful consideration. **Interactions with other medicinal products and other forms of interaction.** None known to date. **Pregnancy and lactation:** Dotarem[®] should be used during pregnancy only if strictly necessary. It is advisable to stop breast-feeding for a few days following the examination with Dotarem[®]. **Undesirable effects:** As for any injection of paramagnetic complex, rare anaphylactic-like reactions exceptionally fatal may occur, requiring an emergency treatment. Very rare general disorders and incidents related to the injection site (extravasation), very rare skin and subcutaneous tissue disorders, very rare nervous system disorders, very rare muscular disorders. **FRENCH PRESENTATION AND MARKETING AUTHORISATION NUMBER:** 358 954.2: 5 mL in vial (glass) - 331 713.4: 10 mL in vial (glass) - 358 953.6: 10 mL in pre-filled syringes (glass) - 331 714.0: 15 mL in vial (glass) - 338 403.0: 15 mL in pre-filled syringes (glass) - 331 715.7: 20 mL in vial (glass) - 338 404.7: 20 mL in pre-filled syringes (glass). GUERBET - BP 57400 - 95943 Roissy CdG Cedex - tel: +33.(0)1.45.91.50.00 (ref.06/07). For detailed information, see Dictionnaire Vidal. Revised: May 2007.

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