

Dotarem®

Gadoteric acid

THE 1ST MACROCYCLIC GBCA*
ON THE MARKET¹

STABILITY
and experience



MORE THAN

140

MILLION DOSES
ADMINISTERED GLOBALLY

Trusted by radiologists,² Dotarem® by Guerbet, a flagship brand known for its high stability,^{3,4} over 30 years of experience^{1,5} with more than 140 million doses administered worldwide,⁶ delivering effective MR contrast-enhanced examination.⁷⁻¹⁰

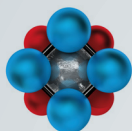
*Gadolinium-based contrast agent

Dotarem®

Gadoteric acid

The most administered macrocyclic GBCA in the world¹¹
+30 years of clinical practice^{1,5}
Approved in over 90 countries globally¹²

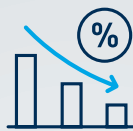
The diagnostic performance and safety profiles are proven by clinical studies and real-world experience^{8-10, 13}



High stability
High kinetic stability and thermodynamic stability^{3,14}



No NSF cases have been reported in patients with a clear history of exposure to Dotarem® alone^{17,18}



Low incidence of immediate adverse events in clinical uses^{8-10, 13, 15-16}



After repeated administration:
No visible T1 hyperintensity detected on non-contrast images in the brain*¹⁹⁻²⁷

*No conclusive published studies in unconfounded cases with Dotarem®.



A large post-marketing study showed:
Good or very good image quality in 98.8% of cases, and a 99% diagnosis established rate⁸



Dotarem® is approved to use in adults, pediatrics, and term neonates[†] for contrast enhancement in whole-body MRI including cerebral, spinal disease and angiography^{‡, 5, 28}

[†] For 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 0.1mmol/kg body weight.

[‡] Angiography is only indicated in patients above 18 years old.



Scan here to discover more about Dotarem®

Scan here to read SmPC

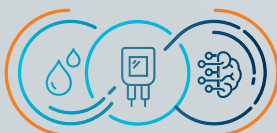


References:

1. Val M. Runge et al., The developmental history of the gadolinium chelates as intravenous contrast media for magnetic resonance. *Invest Radiol.* 2011 Dec;46(12):807-16.
2. Data on file, Guerbet internal data (2022, Q1, Global, Elma market research).
3. Port et al. (2008). Efficiency, thermodynamic and kinetic stability of marketed gadolinium chelates and their possible clinical consequences: a critical review. *Biometals* (2008) 21:469-490.
4. Frenzel et al., Stability of gadolinium-based magnetic resonance imaging contrast agents in human serum at 37 degrees C. *Invest Radiol.* 2008 Dec;43(12):817-28.
5. Dotarem® CCDS -V3- February 2018.
6. Data on file, Guerbet internal data (2021, Q4, Global sales data). Data based on sales estimation and annual results (1989-2021).
7. Braun et al., Baseline characteristics, diagnostic efficacy, and peri-examination safety of IV gadoteric acid MRI in 148,489 patients. *Acta Radiol.* 2020 Jul;61(7):910-920.
8. Soyer et al., Observational study on the safety profile of gadoterate meglumine in 35,499 patients: The SECURE study. *J Magn Reson Imaging.* 2017 Apr;45(4):988-997.
9. Chang DH and Pracros JP. Safety of gadoterate meglumine in over 1600 children included in the prospective observational SECURE study. *Acta Radiol.* 2019 Nov;60(11):1450-1456.
10. K.R. Maravilla et al., Comparison of Gadoterate Meglumine and Gadobutrol in the MRI Diagnosis of Primary Brain Tumors: A Double-Blind Randomized Controlled Intraindividual Crossover Study (the REMIND Study). *AJNR Am J Neuroradiol.* 2017 Sep;36(9):1681-1688.
11. Data on file, Guerbet internal data (2021, Q4, Global). Data inclusive of the MRI contrast agent brands that belong to Bracco imaging S.p.A., G.E Healthcare, Guerbet Group, and Bayer Pharma AG, in the following countries: Algeria, Argentina, Australia, Austria, Belgium, Bosnia, Brazil, Bulgaria, Canada, Caribbean, Chile, China, Columbia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, New Zealand, Norway, Pakistan, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, USA, Venezuela. Data exclude generic brands, except GE (Clariscan™) Bayer (Dotagraf), and local generics in Japan.
12. Data on file, Guerbet internal data (2021, Q4, Global).
13. Eric de Kerviler et al., Adverse Reactions to Gadoterate Meglumine: Review of Over 25 Years of Clinical Use and More Than 50 Million Doses. *Invest Radiol.* 2016 Sep;51(9):544-51.
14. Idee JM et al. Role of thermodynamic and kinetic parameters in gadolinium chelate stability. *Magn Reson Imaging* 2009; 30:1249-1258; 2 (6): 563-576.
15. AH Behzadi et al., Immediate Allergic Reactions to Gadolinium-based Contrast Agents: A Systematic Review and Meta-Analysis. *Radiology.* 2018 Feb;286(2):471-482.
16. McDonald et al., Acute Adverse Events Following Gadolinium-based Contrast Agent Administration: A Single-Center Retrospective Study of 281 945 Injections. *Radiology.* 2019 Sep;292(3):620-627.
17. Dotarem [package insert] (USA). Princeton, NJ: Guerbet LL. April 2020.
18. McWilliams RG et al., Observational Study on the Incidence of Nephrogenic Systemic Fibrosis in Patients With Renal Impairment Following Gadoterate Meglumine Administration: the NSaFe study. *J Magn Reson Imaging.* 2020 Feb;51(2):607-614.
19. McDonald RJ et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology.* 2015 Jun;275(3):7.
20. Radbruch A et al. Gadolinium retention in the dentate nucleus and globus pallidus is dependent on the class of contrast agent. *Radiology.* 2015 Jun;275(3):783-91.
21. Eisele P et al. Lack of increased signal intensity in the dentate nucleus after repeated administration of a macrocyclic contrast agent in multiple sclerosis: An observational study. *Medicine (Baltimore).* 2016 Sep;95(39):e4624.
22. Radbruch A et al. No signal intensity increase in the dentate nucleus on unenhanced T1-weighted MR images after more than 20 serial injections of macrocyclic gadolinium-based contrast agents. *Radiology.* 2017 Jun;282(3):699-707. Epub 2016 Dec 7.
23. Radbruch A et al. Pediatric brain: no increased signal intensity in the dentate nucleus on unenhanced T1-weighted MR images after consecutive exposure to a macrocyclic gadolinium-based contrast agent. *Invest Radiol.* 2016 Nov;51(11):683-690.
24. Quattrocchi CC et al., Standardized assessment of the signal intensity increase on unenhanced T1-weighted images in the brain: the European Gadolinium Retention Evaluation Consortium (GREC) Task Force position statement. *Eur Radiol.* 2019 Aug;29(8):3959-3967.
25. Bennani-Batil B et al., Evaluation of 3.0-T MRI Brain Signal after Exposure to Gadoterate Meglumine in Women with High Breast Cancer Risk and Screening Breast MRI. *Radiology.* 2019 Dec;293(3):523-530.
26. Hannou S et al., Signal Intensity Evaluation in the Dentate Nucleus and Subcortical Gray Matter: Effect of Several Administrations of Gadoterate Meglumine in Multiple Sclerosis. *Clin Neuroradiol.* 2021 Feb 25.
27. Dotarem [package insert] (UK). Roissy CDG. Guerbet. 2017.
28. Dotarem [package insert] (UK). Roissy CDG. Guerbet. 2017.

Dotarem® (Gadoteric Acid) is not registered in all countries. Be aware that indications posology and presentations may differ from country to country. For complete information please refer to country's local SmPC.
© Guerbet Group 2022. P22001418 - July 2022

Dotarem® is part of UNIK, our tailored interconnected solutions for Diagnostic Imaging



UNIK
Tailored interconnected solutions driving your journey to excellence

Guerbet | 
www.guerbet.com