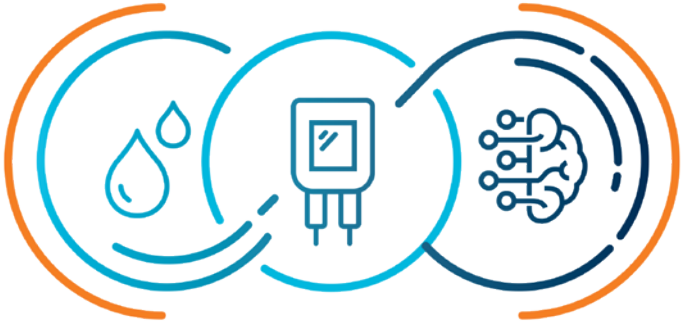
Guerbet

MRI Interconnected Solutions



UNIK

Tailored interconnected solution
driving your journey to excellence

Do you want to discover more?

IMPORTANT SAFETY INFORMATION[1]

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk for NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m^2), or
  - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g. age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended DOTAREM dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Please see additional important Safety information on back page. For more information on DOTAREM, please see Full Prescribing Information, including Boxed Warning and Medication Guide.

UNIK in MRI is Interconnected Solutions with:

CONTRAST AGENT + INJECTOR + DIGITAL SOLUTION + SERVICE & SUPPORT = UNIK

DOTAREM®
(gadoterate meglumine) Injection

☆ Safety
Zero unconfounded cases of NSF & no visible T1 signal intensity detected on non-contrast images within the brain[1, 3]

Low incidence of immediate adverse events[3-10]

☆ Performance
Available in vials and pre-filled syringes (PFS) for an efficient drug delivery-method[1]

☆ Experience
More than 30 YEARS of global experience with more than **100,000,000 GLOBAL DOSES ADMINISTERED**[2]

MORE THAN 30 YEARS

DOTAREM® (gadoterate meglumine) Injection

Start from here

Safety and efficacy established for pediatric patients (including term neonates)[1]

OptiStar® Elite
MRI CONTRAST DELIVERY SYSTEM

☆ Simplicity
One-click loading and auto-retract rams for efficient turnaround

☆ Efficiency
Powerhead keys to allow control at your fingertips

Battery free to save time and cost

☆ Security
Patency check & variable drip mode to test the patient's vein & to maintain the venous access

Contrast&Care
INJECTION MANAGEMENT SOLUTION

☆ Traceability
Facilitate traceability and save administration time

☆ Analytics
Improve your injection practices and optimize contrast media utilization

OptiProtect™
GUERBET SERVICE + SUPPORT

360° technical support available in three service packages

- P PLATINUM
- G GOLD
- S SILVER

An advanced radiology solution for MRI departments and patients

PATIENTS
Designed to add value at each step of the patient healthcare journey

MRI DEPARTMENT
Efficiency
Standardization
(cost-saving & time-saving)

IMPORTANT SAFETY INFORMATION CONTINUED[1]

INDICATIONS AND USAGE
DOTAREM® (gadoterate meglumine) injection is a prescription gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

CONTRAINDICATIONS
History of clinically important hypersensitivity reactions to DOTAREM.

WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions: Anaphylactic and anaphylactoid reactions have been reported with DOTAREM, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of DOTAREM administration and resolved with prompt emergency treatment.
- Before DOTAREM administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to DOTAREM.
- Administer DOTAREM only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, including personnel trained in resuscitation.
- Gadolinium Retention: Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by brain, skin, kidney, liver and spleen. The duration of retention also varies by tissue, and is longest in bone. Linear GBCAs cause more retention than macrocyclic GBCAs.
- Consequences of gadolinium retention in the brain have not been established. Adverse events involving multiple organ systems have been reported in patients with normal renal function without an established causal link to gadolinium retention.
- Acute Kidney Injury: In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging.
- Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of DOTAREM. Extravasation into tissues during DOTAREM administration may result in tissue irritation.

ADVERSE REACTIONS
- The most common adverse reactions associated with DOTAREM in clinical trials were nausea, headache, injection site pain, injection site coldness and rash.
- Serious adverse reactions in the Postmarketing experience have been reported with DOTAREM. These serious adverse reactions include but are not limited to: arrhythmia, cardiac arrest, respiratory arrest, pharyngeal edema, laryngospasm, bronchospasm, coma and convulsion.

USE IN SPECIFIC POPULATIONS
- **Pregnancy:** GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. Use only if imaging is essential during pregnancy and cannot be delayed.
- **Lactation:** There are no data on the presence of gadoterate in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is present in breast milk.
- **Pediatric Use:** The safety and efficacy of DOTAREM at a single dose of 0.1 mmol/kg has been established in pediatric patients from birth (term neonates ≥ 37 weeks gestational age) to 17 years of age based on clinical data. The safety of DOTAREM has not been established in preterm neonates. No cases of NSF associated with DOTAREM or any other GBCA have been identified in pediatric patients age 6 years and younger.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the full Prescribing Information, including the patient Medication Guide, for additional important safety information.

*Dotarem was launched globally in 1989 and approved by the FDA for use in the US in 2013.

REFERENCES:

1. Dotarem [package insert]. Princeton, NJ: Guerbet LLC; Oct 2019. **2.** Internal data as of Oct 2019. **3.** de Kerviler E, Maravilla K, Meder JF, Naggara O 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 doi: 10.1097/RLI.0000000000000276. **4.** Briand et al. Efficacy and safety of the macrocyclic complex Gd-DOTA in Children: Results of a Multi-Centre Study. Proceedings of the 29th Congress of the European Society of Pediatric Radiology. 1992; 128. **5.** Briand Y. Daily Paediatric Use of MRI Contrast Agents: Results of a Multi-Centre Survey. Proceedings of the 29th Congress of the European Society of Pediatric Radiology. 1992. **6.** Ishiguchi T & Takahashi S. Safety of gadoterate meglumine (Gd-DOTA) as a contrast agent for magnetic resonance imaging: results of a post-marketing surveillance study in Japan. Drugs R D. 2010;10(3):133-45. **7.** Emond S & Brunelle F. Gd-DOTA administration at MRI in children younger than 18 months of age: immediate adverse reactions. Pediatr Radiol. 2011 Nov;41(11):1401-6. **8.** Maurer M et al. Tolerability and diagnostic value of gadoteric acid in the general population and in patients with risk factors: results in more than 84,000 patients. Eur J Radiol. 2012 May;81(5):885-90. **9.** Soyer et al. Observational Study on the Safety Pro le of Gadoterate Megluminein 35,499 Patients: The SECURE Study. J. Magn. Reson. Imag. 2017; 45, 988-997 **10.** 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):783-97.

The OptiStar® Elite MR Contrast Delivery System is a Class II Medical Device in the United States. For complete information about precautions and optimal usage conditions for this device, consult the full instructions for use supplied with each device or with your local Guerbet representative(s).

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

Contrast&Care® is a medical device intended for use by healthcare professionals only. It allows imaging centers to collect, archive, view and share patients' injection data, including data concerning contrast products, adverse events, injector activity, data on the estimated eGFR and other pre-exam alerts, such as previously reported allergies.

Contrast&Care® also provides options to visualize analytics data and trends relating to injection activity and contrast product usage.

For complete information about precautions and optimal usage conditions, we recommend consulting the instructions for use supplied with the device or by your local Guerbet representative(s).

Class I
Manufacturer: Medex

Guerbet

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CONTACT

If you need more information,
feel free to contact your sales representative