



Expanding our portfolio to increase your options from GE HealthCare

Macrocyclic gadoterate meglumine



GE HealthCare expertise



Clariscan™
(gadoterate meglumine)
injection for intravenous use



IMPORTANT SAFETY INFORMATION ABOUT CLARISCAN™ (GADOTERATE MEGGLUMINE)

PRODUCT INDICATIONS AND USE:

CLARISCAN™ (gadoterate meglumine) 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.

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Risk Associated with Intrathecal Use

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. CLARISCAN is not approved for intrathecal use.

Nephrogenic Systemic Fibrosis

GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of CLARISCAN in these patients unless the diagnostic information is essential and not available with non-contrast 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/1.73m²), 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 CLARISCAN dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

CONTRAINDICATIONS

History of clinically important hypersensitivity reactions to CLARISCAN.

WARNINGS AND PRECAUTIONS

- **Risk Associated with Intrathecal Use:** Intrathecal administration of GBCAs can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of CLARISCAN have not been established with intrathecal use. CLARISCAN is not approved for intrathecal use.
- **Nephrogenic Systemic Fibrosis:** GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of CLARISCAN among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.
- **Hypersensitivity Reactions:** Anaphylactic and anaphylactoid reactions have been reported with CLARISCAN, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died.
- Before CLARISCAN 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 CLARISCAN.

- **Gadolinium Retention:** Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver and spleen). While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.
- **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 CLARISCAN. Extravasation into tissues during CLARISCAN administration may result in tissue irritation.

ADVERSE REACTIONS

- In clinical trials, the most frequent adverse reactions that occurred in > 0.2% of patients who received CLARISCAN included: nausea, headache, injection site pain, injection site coldness and rash.
- Serious adverse reactions in the Postmarketing experience have been reported with CLARISCAN. 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 of CLARISCAN has not been established in preterm neonates. No dosage adjustment according to age is necessary in pediatric patients.
- **Geriatric Use:** Use of CLARISCAN in elderly patients should be cautious, reflecting the greater frequency of impaired renal function and concomitant disease or other drug therapy. No age-related dosage adjustment is necessary.
- **Renal Impairment:** No CLARISCAN dosage adjustment is recommended for patients with renal impairment.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1-800-654-0118 or by email at gpv.drugsafety@gehealthcare.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see [CLARISCAN full Prescribing Information](#), including the Medication Guide, for additional important safety information.

Clariscan™
(gadoterate meglumine)
injection for intravenous use

Advancing at a remarkable rate, MRI has added to the information used in diagnosing an array of conditions, monitoring treatment, and disease management

- From neurology to oncology, MRI has had a huge impact in just a few decades^{1,2}
- Such progress has been made possible through collaboration – both between disciplines and within industry³

GE HealthCare is proud to be part of the continual evolution of MRI

1973	1982	1993	2003	2009	2016	2017	2019
Paul Lauterbur, PhD, first demonstrates use of NMR images	We deliver the first clinically viable whole-body MRI scanner	We launch the first nonionic CM for MRI	We introduce the first MRI motion correction technique	Our researcher, Dr. J. Schenck, receives the ISMRM's highest honor	We innovate a <10 min, 4D flow cardiac MRI exam	We launch the AIR Technology™ coil to truly conform to the body	We launch CLARISCAN™ (gadoterate meglumine) injection for intravenous use

Technical and scientific advances, and the resultant effect on patients, are set to continue at an ever-expanding and truly remarkable pace⁴

Clariscan™
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CM, contrast medium; ISMRM, International Society for Magnetic Resonance in Medicine; MRI, magnetic resonance imaging; NMR, nuclear magnetic resonance.

Expanding our portfolio, we can provide a macrocyclic agent expertly manufactured by GE HealthCare

- Stability is one of the important considerations in GBCA choice⁵
- Although all approved GBCAs have been demonstrated to be safe and effective, the market is shifting toward macrocyclic agents⁶

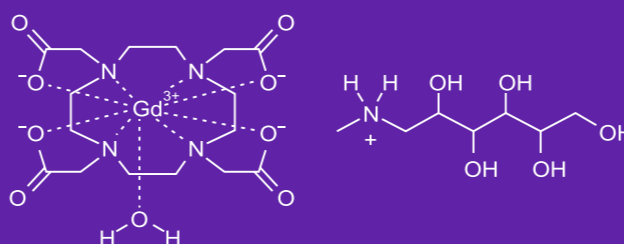
CLARISCAN™ (gadoterate meglumine) injection for intravenous use

Macrocyclic, ionic GBCA

Cage-like structure encloses the Gd³⁺ ion⁵

Highest chelate stability among GBCAs⁷

Strong chemical bond⁸



GE HealthCare

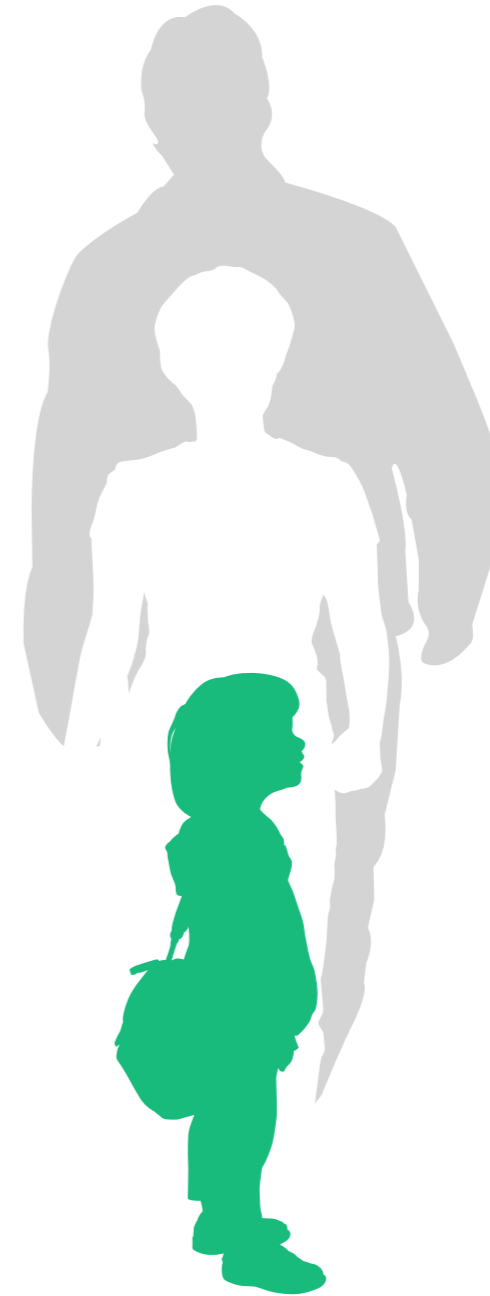
Please see Full Prescribing Information for Clariscan, including Boxed Warning and Medication Guide, for additional important safety information. Click [here](#) to access the Full Prescribing information.

GBCA, gadolinium-based contrast agent; Gd, gadolinium.

Clariscan™
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Providing an option for everyday practice⁹

Clariscan is a 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.



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GBCA, gadolinium-based contrast agent; Gd, gadolinium.

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Clariscan™ is appropriate for use in specific populations⁹:

- The elderly
- Pediatric patients from birth (term neonates ≥ 37 weeks gestational age)

During pregnancy, use only if imaging is essential and cannot be delayed

Recommended dose	0.2 mL/kg (0.1 mmol/kg) body weight	
Flow rate	Adults	Children
	~2 mL/second	1-2 mL/second

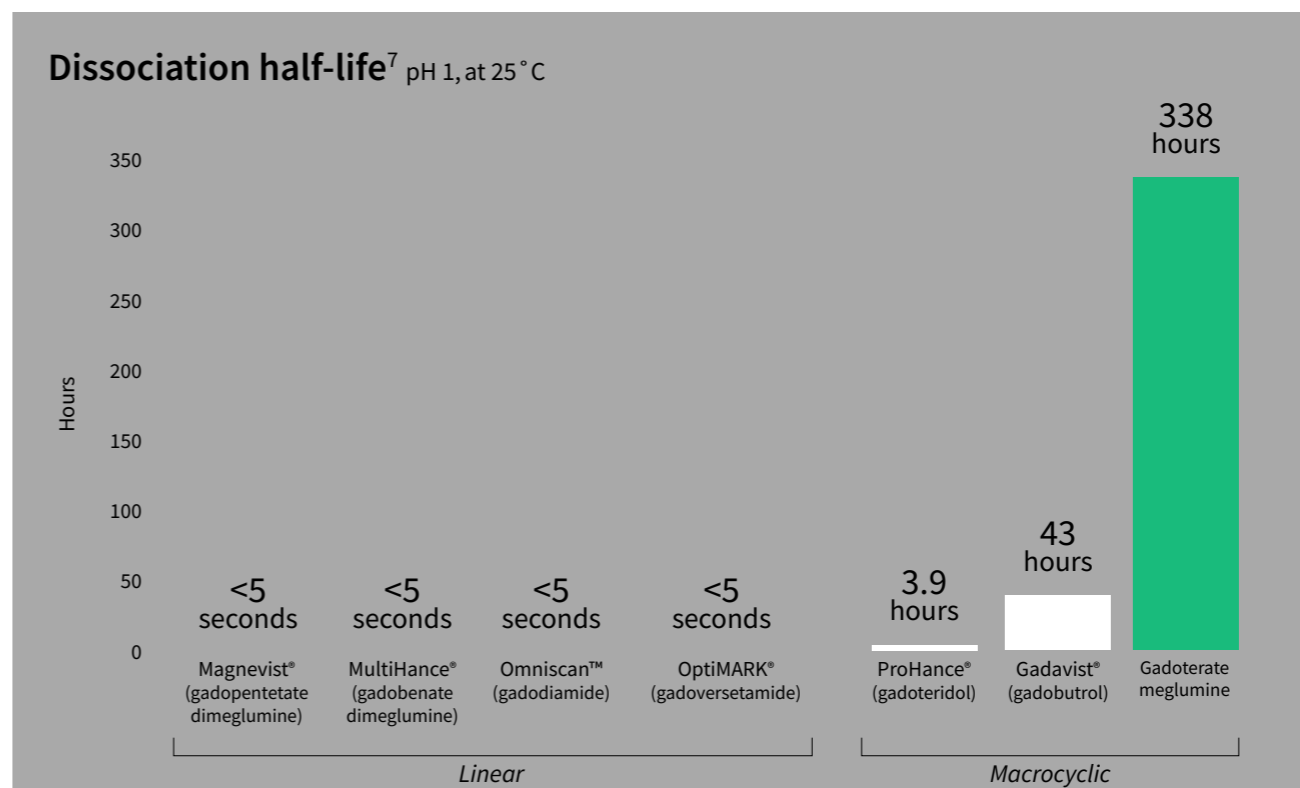
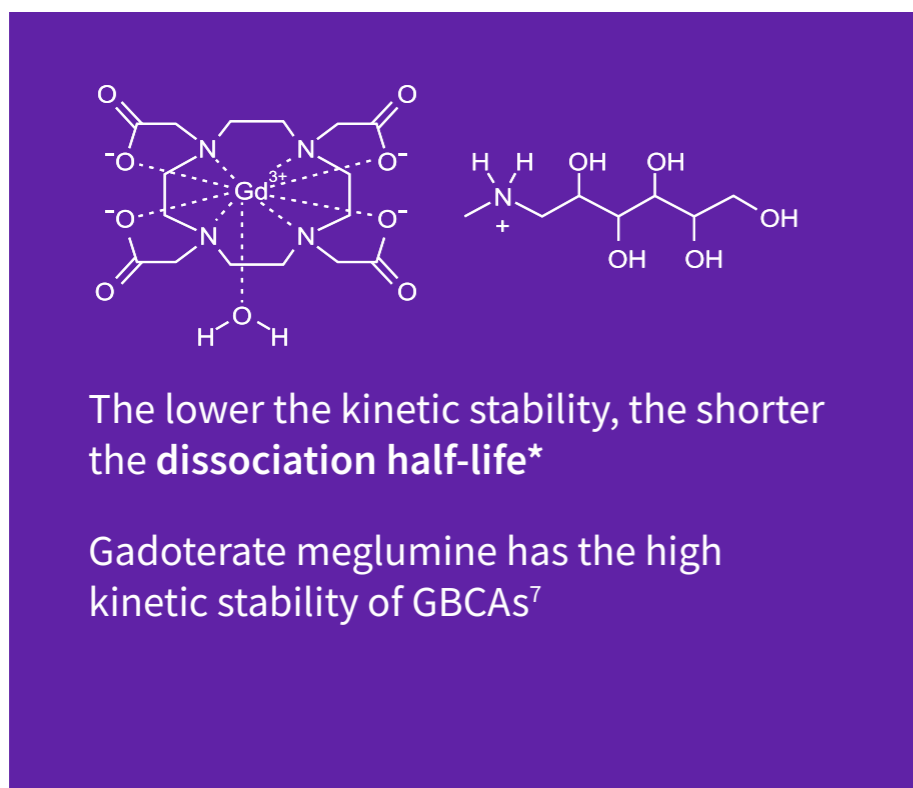
Please see dosing table in Section 2.1 of the full Prescribing Information for more detailed information.

No dose adjustment of Clariscan is recommended for patients with renal impairment.

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Clariscan™
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Combining a macrocyclic structure for high kinetic stability...⁷



Adapted from Port et al.⁷

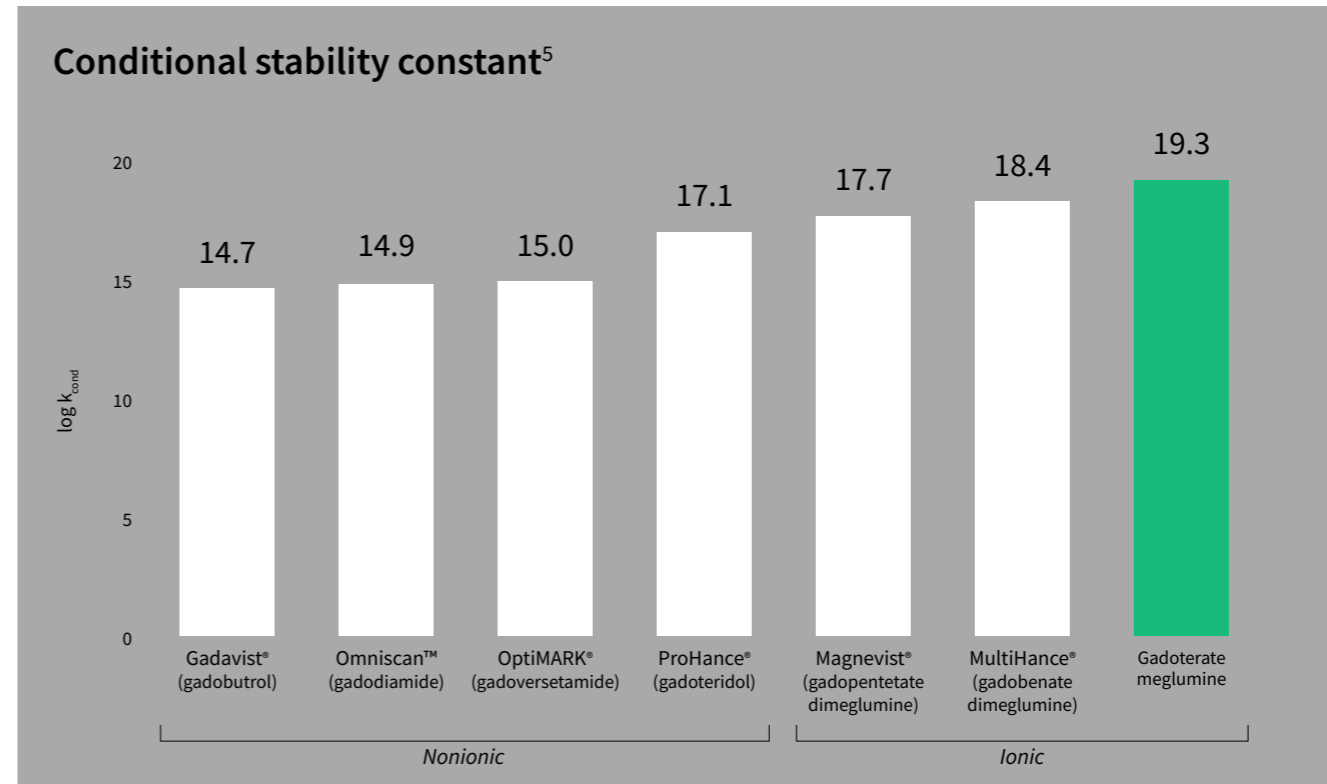
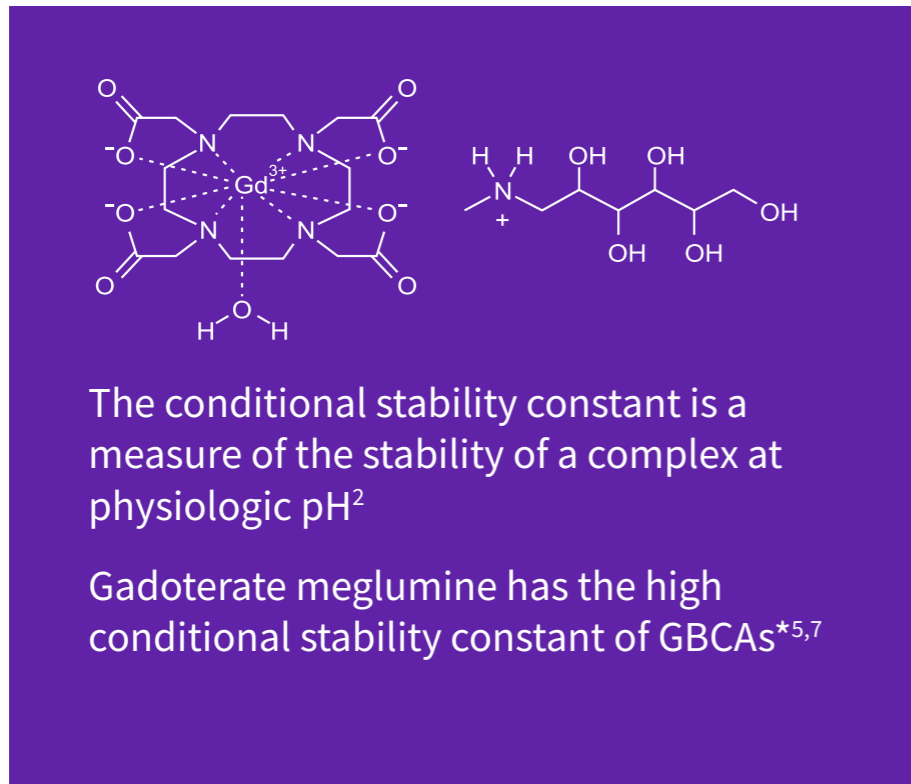
***Data from in vitro studies; the clinical significance of these data is unknown.**

Magnevist (gadopentetate dimeglumine) and Gadavist (gadobutrol) are registered trademarks of Bayer HealthCare Pharmaceuticals Inc. MultiHance (gadobenate dimeglumine) Injection and ProHance (gadoteridol) Injection are registered trademarks of Bracco Diagnostics Inc. OptiMARK (gadoversetamide) Injection is a registered trademark of Guerbet LLC.

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...with ionicity for thermodynamic stability^{5,7}



Adapted from Tweedle et al.⁵

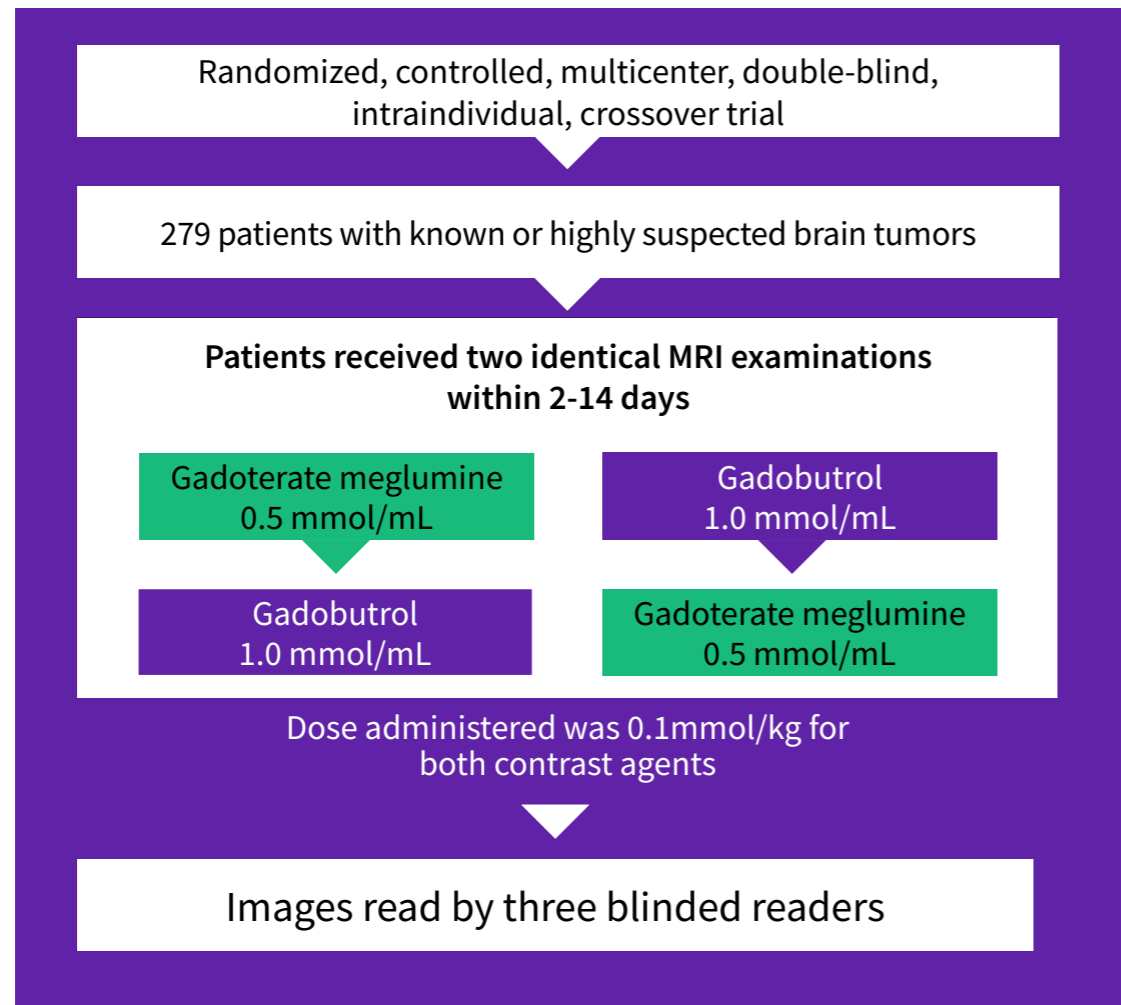
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Comparison of gadoterate meglumine and gadobutrol in the MRI of primary brain tumors: The REMIND study¹⁰



Rate of patients with overall lesion visualization and characterization scored good/excellent¹⁰

Reader 1		Reader 2		Reader 3	
Gadobutrol	Gadoterate meglumine	Gadobutrol	Gadoterate meglumine	Gadobutrol	Gadoterate meglumine
94.0%	96.2%	93.2%	90.6%	99.6%	100.0%

The noninferiority of gadoterate meglumine versus gadobutrol for overall visualization and characterization of primary brain tumors was demonstrated¹⁰

Data shown related to gadoterate meglumine were not derived from a study using Clariscan, but Clariscan is AP rated to the study drug.

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API, active pharmaceutical ingredient; GBCAs, gadolinium-based contrast agents; MRI, magnetic resonance imaging.

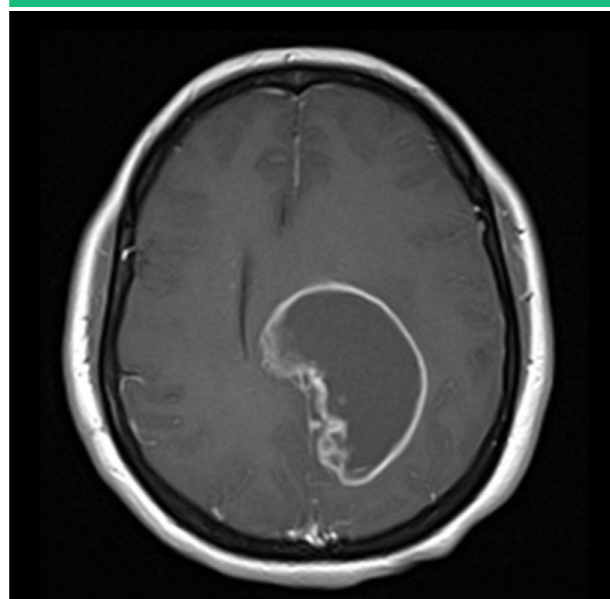
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46-year-old female patient

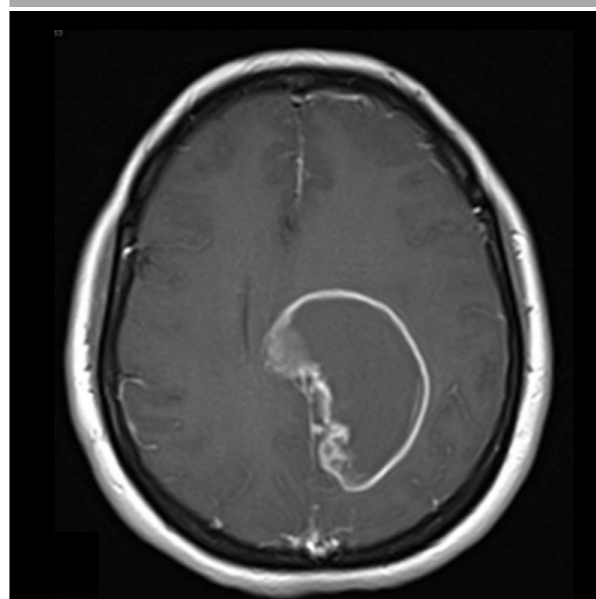
Glioblastoma

T1 spin-echo images were acquired using:

A: Gadoterate meglumine



B: Gadavist® (gadobutrol)



Lesion visualization and characterization were scored as excellent by all three blinded readers; the enhancing rim of the lesion is clearly seen on both examinations.

Imaging results may vary among patients. Images taken from publication.

A similar percentage of AEs related to both contrast agents was observed: Gadoterate meglumine (7.8%, n=20 patients) vs gadobutrol (7.3%, n=19 patients). All AEs related to both the contrast agents were mild or moderate in intensity and were resolved.

This multicenter, randomized, double-blind, controlled intraindividual crossover study demonstrated that despite the difference in concentration and relaxivity between these two GBCAs, no measurable difference in clinical benefit was observed.^{10}*

*Limitations: Histopathologic confirmation ensuring the validity of the diagnosis was lacking. The impact of contrast-enhanced MRI on patient medical management was not evaluated. Nearly 60% of patients presented with extra-axial tumors, meningiomas, or nerve sheath tumors, which should readily enhance regardless of agent and magnetic field strength. Clinical benefit was defined as noninferiority of the images.

Gadavist (gadobutrol) is a registered trademark of Bayer HealthCare Pharmaceuticals Inc.

Republished with permission of the American Journal of Neuroradiology from Comparison of the Gadoterate Meglumine and Gadobutrol in the MRI Diagnosis of Primary Brain Tumors: A Double-Blind Randomized Controlled Intraindividual Crossover Study (the REMIND Study), K.R. Maravilla et al, vol. 38.

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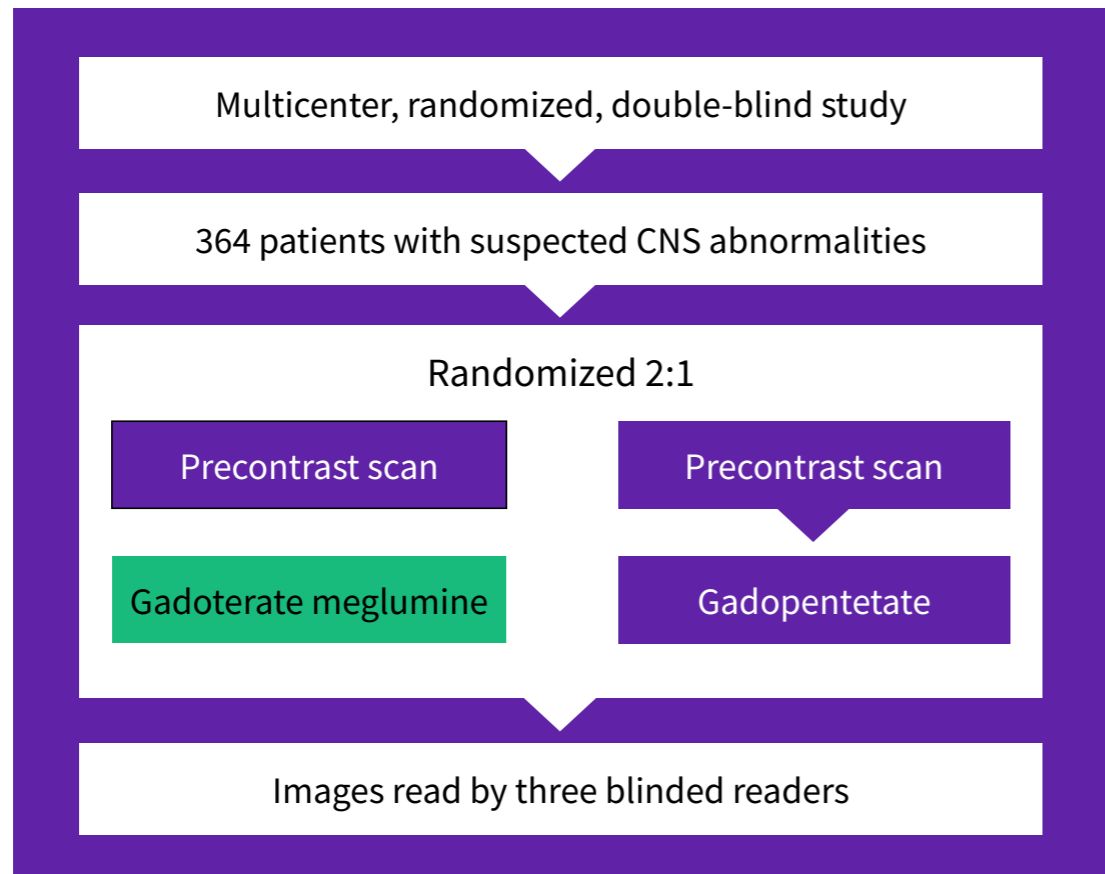
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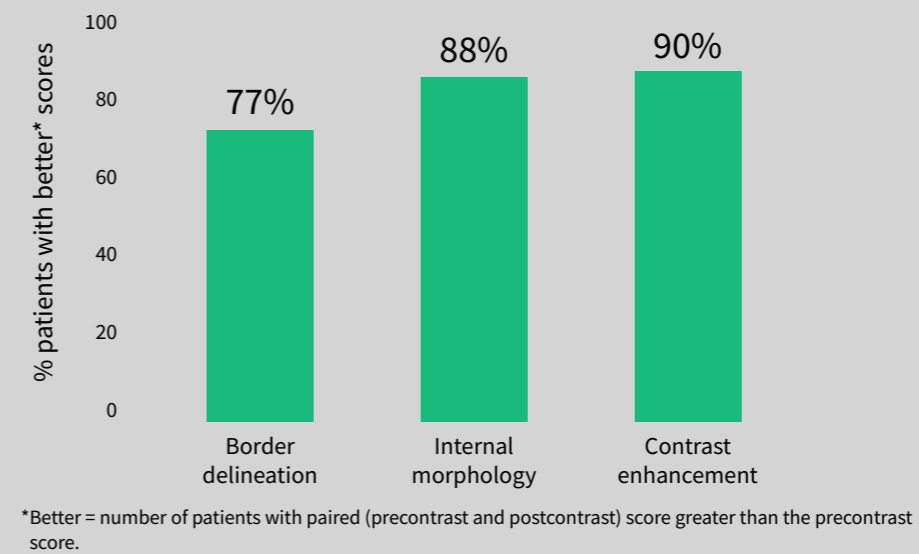
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Safety and efficacy evaluation of gadoterate meglumine in MRI of patients with CNS lesions (SENTIO study)^{9,11}



Improvement in visualization score with gadoterate meglumine vs precontrast images^{9,11}



Efficacy results were statistically comparable between gadoterate meglumine and gadopentetate ($P < 0.001$)¹²

Safety profiles were comparable between the two agents¹²

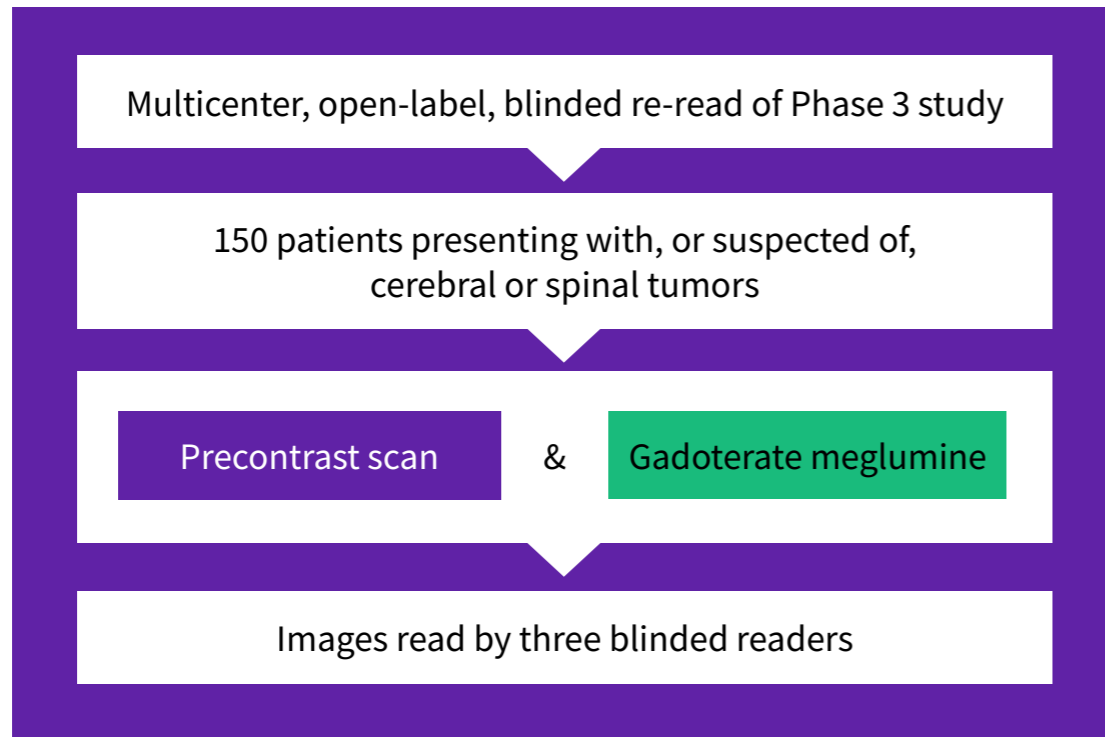
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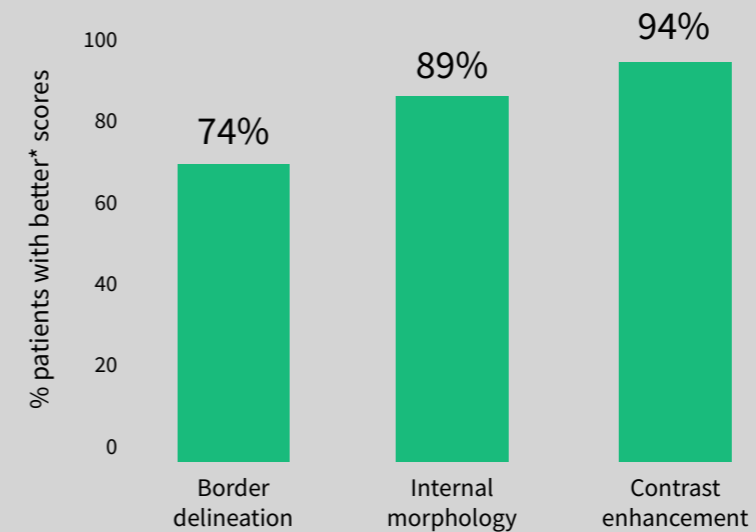
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Efficacy of gadoterate meglumine-enhanced MRI in the characterization of cerebral and spinal tumors⁹



Lesion visualization scores, precontrast vs gadoterate meglumine enhanced scans¹²



*Better = number of patients with paired (precontrast and postcontrast) score greater than the precontrast score.

All prospectively defined primary and secondary efficacy endpoint analyses were positive and support the effectiveness of gadoterate meglumine for use in MRI of the CNS¹²

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API, active pharmaceutical ingredient; CNS, central nervous system; MRI, magnetic resonance imaging.

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Adverse reactions seen with gadoterate meglumine

Adverse reactions that occurred in $\geq 0.2\%$ of patients who received gadoterate meglumine from clinical studies experience⁹

Reaction	Rate (%) n=2867
Nausea	0.6%
Headache	0.4%
Injection-site pain	0.4%
Injection-site coldness	0.2%
Rash	0.2%

Adverse reactions that occurred with a frequency $< 0.2\%$ in patients who received gadoterate meglumine include: feeling cold, feeling hot, burning sensation, somnolence, pain, dizziness, dysgeusia, blood creatinine increased, hypotension, hypertension, asthenia, fatigue, injection site reactions (inflammation, extravasation, pruritus, swelling, warmth), paresthesia, pruritus, laryngeal discomfort, pain in extremity, vomiting, anxiety and palpitations.

Adverse reactions in pediatric patients⁹

During clinical trials, 185 pediatric patients (52 aged < 24 months, 33 aged 2 – 5 years, 57 aged 6 – 11 years and 43 aged 12 – 17 years) received gadoterate meglumine. Overall, 7 pediatric patients (3.8%) reported at least one adverse reaction following gadoterate meglumine administration. The most frequently reported adverse reaction was headache (1.1%). Most adverse events were mild in intensity and transient in nature.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in clinical practice

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Adverse reactions seen with gadoterate meglumine (cont'd)

The following additional adverse reactions have been identified during postmarketing use of gadoterate meglumine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.⁹

Adverse reactions in the postmarketing experience ⁹	
System organ class	Adverse reaction
Cardiac disorders	bradycardia, tachycardia, arrhythmia
Immune system disorders	hypersensitivity/anaphylactoid reactions including cardiac arrest, respiratory arrest, cyanosis, pharyngeal edema, laryngospasm, bronchospasm, angioedema, conjunctivitis, ocular hyperemia, eyelid edema, lacrimation increased, hyperhidrosis, urticaria
Nervous system disorders	coma, convulsion, syncope, presyncope, parosmia, tremor
Musculoskeletal and connective tissue disorders	muscle contracture, muscle weakness
Gastrointestinal disorders	diarrhea, salivary hypersecretion
General disorders and administration site conditions	malaise, fever Adverse events with variable onset and duration have been reported after GBCA administration [see Warnings and Precautions (5.3)]. These include fatigue, asthenia, pain syndromes, and heterogeneous clusters of symptoms in the neurological, cutaneous, and musculoskeletal systems.
Skin and subcutaneous tissue disorders	NSF, in patients whose reports were confounded by the receipt of other GBCAs or in situations where receipt of other GBCAs could not be ruled out. No unconfounded cases of NSF have been reported with gadoterate meglumine. Gadolinium-associated plaques.
Vascular disorders	superficial phlebitis

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Simple ordering process, and packaging with a 2D Data Matrix to transfer important information

National Drug Codes (NDCs)/SKUs



Fill size	5mL in glass vial	10 mL in glass vial	15 mL in glass vial	20 mL in glass vial	10 mL in 20 mL prefilled syringe	15 mL in 20 mL prefilled syringe	20 mL in 20 mL prefilled syringe	100 mL +PLUSPAK polymer bottle
NDC	0407-2943-06	0407-2943-01	0407-2943-02	0407-2943-05	0407-2943-12	0407-2943-17	0407-2943-22	0407-2943-70
SKU	C105	C110	C115	C120	C210	C215	C220	C300

10

Each fill size can be ordered in packs of 10.
Contact your GE HealthCare Account Manager or Customer Service at 800 292 8514 for more information.



With a 2D Data Matrix on each vial and outer box of 10 vials, information can be scanned rather than entered manually.

Each 2D Data Matrix will contain the following information:
• NDC • Expiration date • Lot number

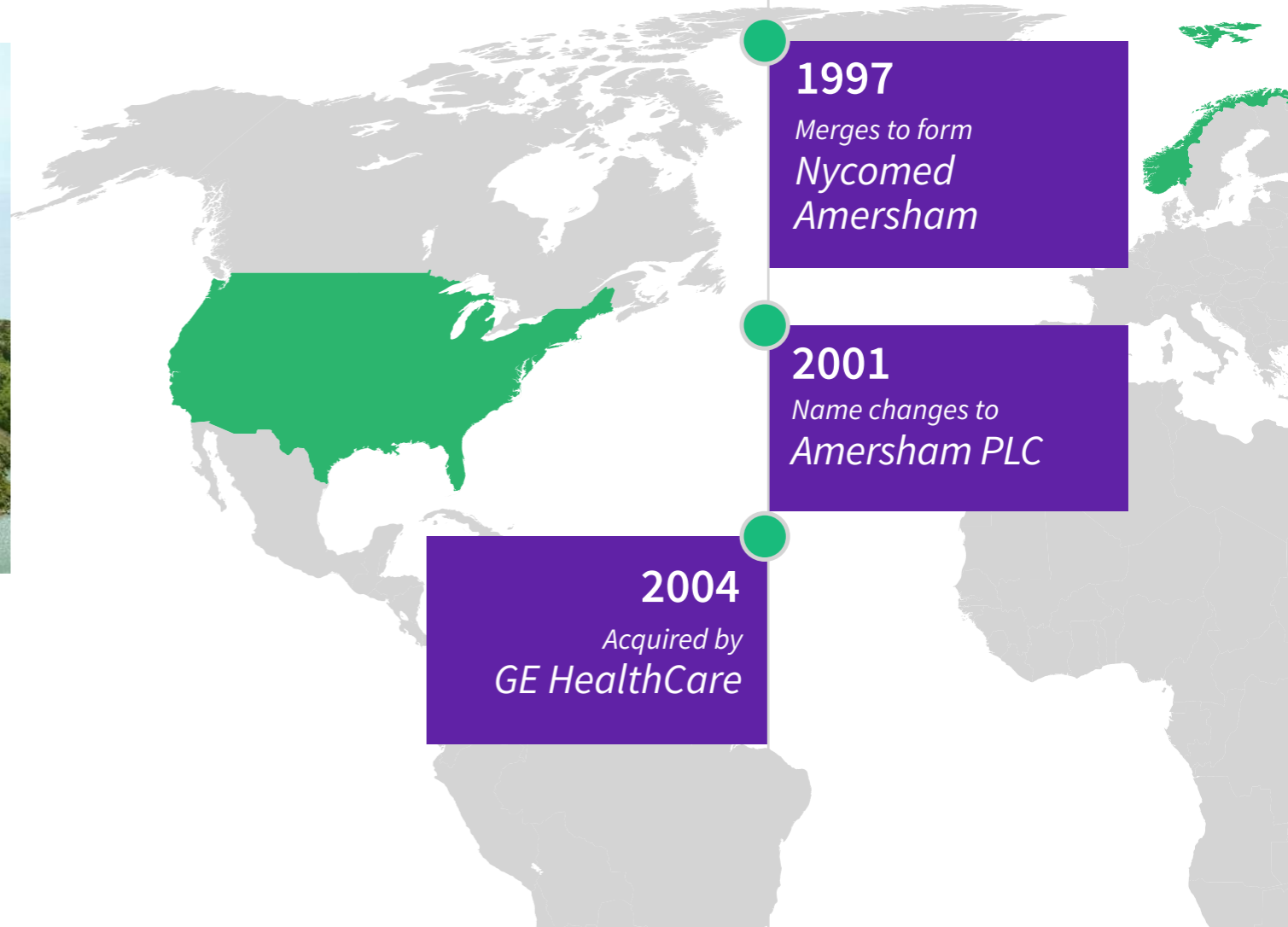
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Delivering contrast media from our production site in Norway to customers in the United States for more than 40 years



Today, approximately one-half of all contrast-enhanced X-ray/CT examinations in the US are performed with a contrast medium from GE HealthCare¹³



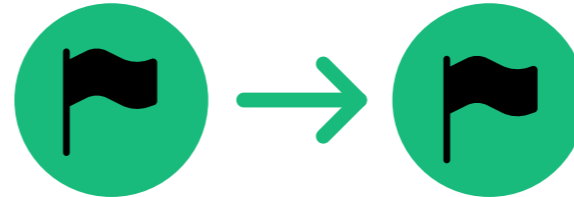
Clariscan™
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CT, computed tomography; MRI, magnetic resonance imaging.

Keeping all production in-house, so you can be assured that standards are maintained from start to finish



As with our other contrast media products, from API production to final product, every stage of manufacturing is managed entirely by GE HealthCare.



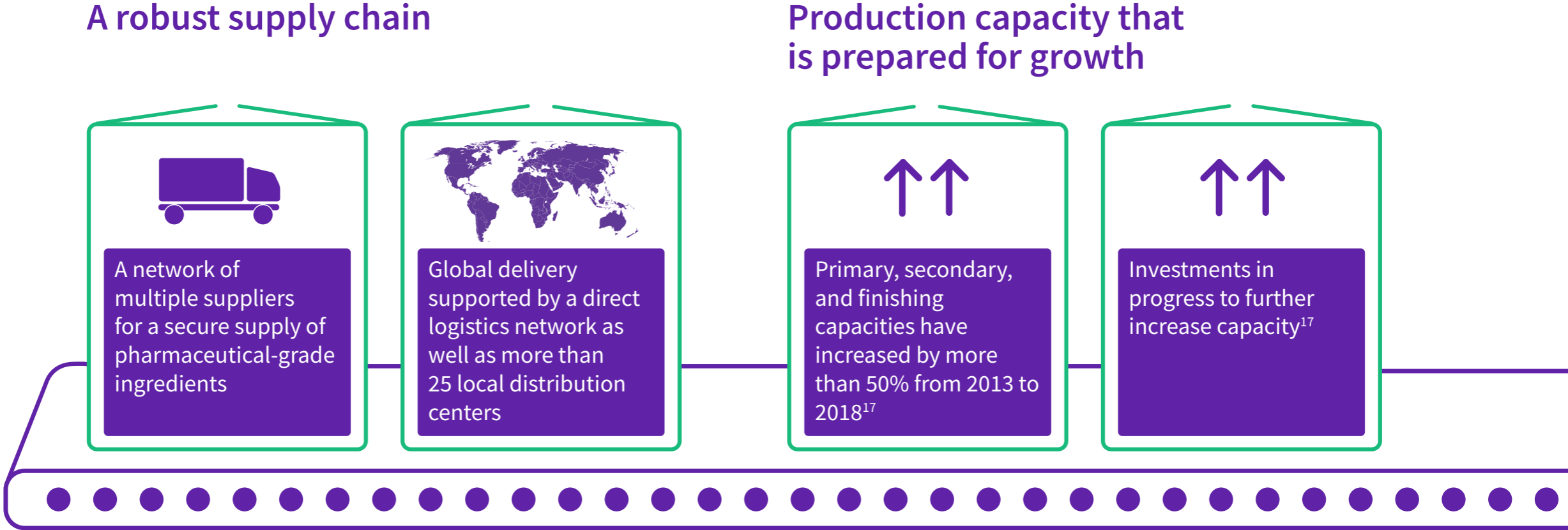
Clariscan is produced in compliance with cGMP within predefined specifications as approved by the FDA¹⁴

As of 2019, 20% of our employees work in quality control/quality assurance to help maintain consistently high standards of production¹⁵

All of our production sites are cGMP-accredited

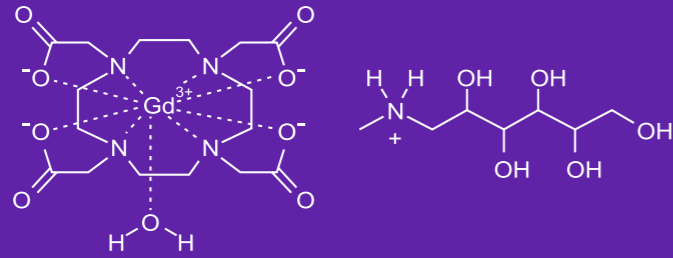
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Investing in infrastructure, so you can trust in reliable delivery when you schedule your procedures



Clariscan™
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injection for intravenous use

Consider CLARISCAN™ (gadoterate meglumine) injection for intravenous use to increase your options



Gadoterate
meglumine



GE HealthCare

Macrocyclic molecule



Expertise and
commitment

Established contrast
media heritage



Ongoing investment

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16. Data on file. GE HealthCare Inspection; 2018.
17. Data on file. GE HealthCare Investment; 2018.

Support for Clariscan

GE HealthCare Reimbursement Support Line

GE HealthCare is pleased to offer toll-free customer support and documentation for coding and reimbursement related to our products. Please contact us at 800 767 6664.

Customer Service

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Medical Affairs

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