



**FRESENIUS
KABI**

caring for life

Gadoterate Meglumine Injection, USP

FDA-approved, cost-effective generic gadolinium-based contrast agent (GBCA) is bioequivalent and fully substitutable to Dotarem®*



WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

See full prescribing information for complete boxed warning

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-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 less than 30 mL/min/1.73 m²), 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 more than 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 Gadoterate Meglumine Injection dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Please see Important Safety Information on the following pages.

Gadoterate Meglumine Injection, USP

Macrocyclic & Ionic Gadolinium-Based Contrast Agent



Fresenius Kabi's FDA-approved generic Gadoterate Meglumine Injection, USP provides a cost-effective option that is bioequivalent and fully substitutable to Dotarem®.*

Gadoterate Meglumine Injection 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.¹

The use of a gadolinium (Gd)-based contrast agent (GBCA) further increases the diagnostic sensitivity and capabilities of MRI. In the United States, GBCAs are used in 30% to 45% of the approximately 40 million MRI procedures performed each year.²

Generic medicines are the same high quality as their brand-name versions.³

Generic drugs go through a rigorous review process to receive FDA approval. The FDA ensures a generic medication provides the same clinical benefit and is as safe and effective as the brand-name medicine. Generic contrast agents are considered generic drugs by the FDA. To learn more about generic drugs visit www.FDA.gov/GenericDrugs.

A Cost-Effective Option from an Experienced, Reliable Supplier

Committed to Helping You

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition - with a comprehensive portfolio of injectable drugs and delivery systems used to treat a broad spectrum of patients. As a leading provider of generic medications, we leverage our 100-year history to deliver innovative therapies that are safe, effective and affordable. **That's how Fresenius Kabi brings confidence within reach.**

Sources:

1. Gadoterate Meglumine Injection Package Insert, August 2023
2. Cheong BYC, Wilson JM, Preventza OA, Muthupillai R. Gadolinium-based contrast agents: updates and answers to typical questions regarding gadolinium use. *Tex Heart Inst J* 2022; 49(3):e217680. doi:10.14503/THIJ-21-7680
3. FDA, Generic Drug Facts Handout <https://www.fda.gov/media/107601/download>

IMPORTANT SAFETY INFORMATION

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Contraindications: Gadoterate Meglumine Injection is contraindicated in clinically important hypersensitivity reactions to Gadoterate Meglumine Injection.

Warning and Precautions

Hypersensitivity Reactions: Anaphylactic and anaphylactoid reactions have been reported with gadoterate meglumine, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of gadoterate meglumine administration and resolved with prompt emergency treatment. Before Gadoterate Meglumine Injection 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 Gadoterate Meglumine Injection. Administer Gadoterate Meglumine Injection 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 (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (e.g., 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.

Fresenius Kabi's Gadoterate Meglumine Injection, USP is fully substitutable and chemically equivalent to Dotarem®.*

	Reference Listed Drug					Approved AP Generic					Therapeutically Equivalent
Name	Dotarem® ¹					Gadoterate Meglumine Injection, USP ²					
Indication	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.					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.					✓
Features	Sterile, nonpyrogenic, clear, colorless to yellow, aqueous solution. No preservative is added.					Sterile, nonpyrogenic, clear, colorless to yellow, aqueous solution. No preservative is added.					✓
Concentration	0.5 mmol per mL (Each mL of Gadoterate Meglumine Injection, USP contains 376.9 mg of gadoterate meglumine)					0.5 mmol per mL (Each mL of Gadoterate Meglumine Injection, USP contains 376.9 mg of gadoterate meglumine)					✓
Ingredients	Active Ingredient: gadoterate meglumine Inactive Ingredients: DOTA, water for injection					Active Ingredient: gadoterate meglumine Inactive Ingredients: DOTA, water for injection					✓
Vial Presentations	5 mL Single Dose Vial	10 mL Single Dose Vial	15 mL Single Dose Vial	20 mL Single Dose Vial	100 mL Pharmacy Bulk Package	5 mL Single Dose Vial	10 mL Single Dose Vial	15 mL Single Dose Vial	20 mL Single Dose Vial	100 mL Pharmacy Bulk Package	✓
Concentration	2.5 mmol per mL	5 mmol per mL	7.5 mmol per mL	10 mmol per mL	50 mmol per mL	2.5 mmol per mL	5 mmol per mL	7.5 mmol per mL	10 mmol per mL	50 mmol per mL	✓
Parameter	Value					Value					✓
Density @20°C	1.1753 g/cm ³					1.1753 g/cm ³					✓
Viscosity @20°C	3.4 mPa·s					3.4 mPa·s					✓
Viscosity @37°C	2.4 mPa·s					2.4 mPa·s					✓
Osmolality	1,350 mOsm/kg water					1,350 mOsm/kg water					✓
Log K_{therm}	25.6					25.6					✓
Log K_{cond} (pH 7.4)	19.3					19.3					✓
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).					Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).					✓

1. Dotarem Package Insert, April 2019

2. Gadoterate Meglumine Injection Package Insert, August 2023

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 Gadoterate Meglumine Injection. Extravasation into tissues during Gadoterate Meglumine Injection administration may result in tissue irritation

Adverse Reactions: The most frequent (≥ 0.2%) adverse reactions in clinical studies were nausea, headache, injection site pain, injection site coldness, and rash.

Serious adverse reactions in the Postmarketing experience have been reported with Gadoterate Meglumine Injection. These serious adverse reactions include but are not limited to: arrhythmia, cardiac arrest, respiratory arrest, pharyngeal edema, laryngospasm, bronchospasm, coma and convulsion.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 gadoterate meglumine at a single dose of 0.1 mmol/kg have 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 gadoterate meglumine has not been established in preterm neonates.

Indications and Usage

Gadoterate Meglumine Injection 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.

This Important Safety Information does not include all the information needed to use Gadoterate Meglumine Injection, USP safely and effectively. Please see full prescribing information, including BOXED WARNING, for Gadoterate Meglumine Injection, USP at www.fresenius-kabi.com/us.



Gadoterate Meglumine Injection, USP

- FDA-approved, AP Rated
- Macrocylic¹
- Ionic¹
- Preservative Free¹
- The container closure is not made with natural rubber latex
- Bioequivalent and fully substitutable to Dotarem®*

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Unit of Sale NDC	Description	Concentration	Fill Volume (mL)	Unit of Sale
65219-080-05	Single Dose Vial	0.5 mmol per mL	5 mL	10
65219-082-10	Single Dose Vial	0.5 mmol per mL	10 mL	10
65219-084-15	Single Dose Vial	0.5 mmol per mL	15 mL	10
65219-086-20	Single Dose Vial	0.5 mmol per mL	20 mL	10
65219-088-50	Pharmacy Bulk Package	0.5 mmol per mL	100 mL	6

1. Gadoterate Meglumine Injection Package Insert, August 2023

*Dotarem® is a registered trademark of Guerbet.

Ordering Information

Please contact your account representative or our Customer Service Department Monday through Friday, 7:00AM - 6:00PM (CST) at:

Toll-Free: (888) 386-1300

Fax: (800) 743-7082

E-mail: customerservice.usa@fresenius-kabi.com

For more information visit: GenericContrastAgents.com

If you are interested in establishing a new account with Fresenius Kabi USA, contact us for additional information and necessary forms.

Please see [package insert](#) for full prescribing information, including **BOXED WARNING**, for Gadoterate Meglumine Injection. Full prescribing information is also available at www.fresenius-kabi.com/us.



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