Contrast Agents Portfolio

- Cost-Effective Contrast Agents
- FDA-Approved, AP Rated
- Fully Substitutable to Brand Products
- Preservative Free
- Container closure is not made with natural rubber latex

Generic CT and MRI Contrast Agents

Options to provide you with *choice* and *value* from the leading provider of generic contast agents.

FRESENIUS KABI

Every Scan Tells a Story

It is said that a picture is worth a thousand words. Radiology-related scans help tell stories that may contribute to the diagnosis process for patients. Contrast agents are used to help improve the visibility of internal structures and tissues during medical imaging by increasing the contrast between different types of body tissue. The use of contrast agents may help doctors identify abnormalities and make diagnoses.

Whether it's a computed tomography (CT) or magnetic resonance imaging (MRI), Fresenius Kabi understands the importance of these scans. After all, we are the leader in providing generic contrast agents. To help you diversify suppliers so that you have the supply you and your patients need, we have invested in the market to continually increase our supply of generic contrast agents.

Leading Provider

Generic Contrast Agents

The 2022 contrast agent shortage exposed the need to diversify manufacturers. During the global CT contrast agent shortage, Fresenius Kabi maintained supply for our customers; we worked to increase production and even used air freight to quickly get product to health care providers so they could give patients the care they needed. Since then, we have continued to uphold our commitment to being a reliable partner.

We also currently have two MRI contrast options available so you can choose what's right for you and your patients.

Our commitment is to provide you with choice and value – by continuing to grow our portfolio of cost-effective generic contrast agents.

Now You Have a Choice

Partner with Fresenius Kabi

In today's world, having only one source of supply can be challenging. Keep your options open by expanding your choices. Diversify your options with a leading provider of generic injectable pharmaceuticals.

Fresenius Kabi has expanded our radiology portfolio to include cost-effective products, including the CT and MRI contrast agents featured in this catalog.

By partnering with Fresenius Kabi, you will have access to FDA-approved generics that are fully substitutable to the brand-name products – at a lower cost. **Now you have a choice.**

CT

MRI

Get Clarity on Generics

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 and brand-name medicines have the same:

ACTIVE INGREDIENTS

SAFETY

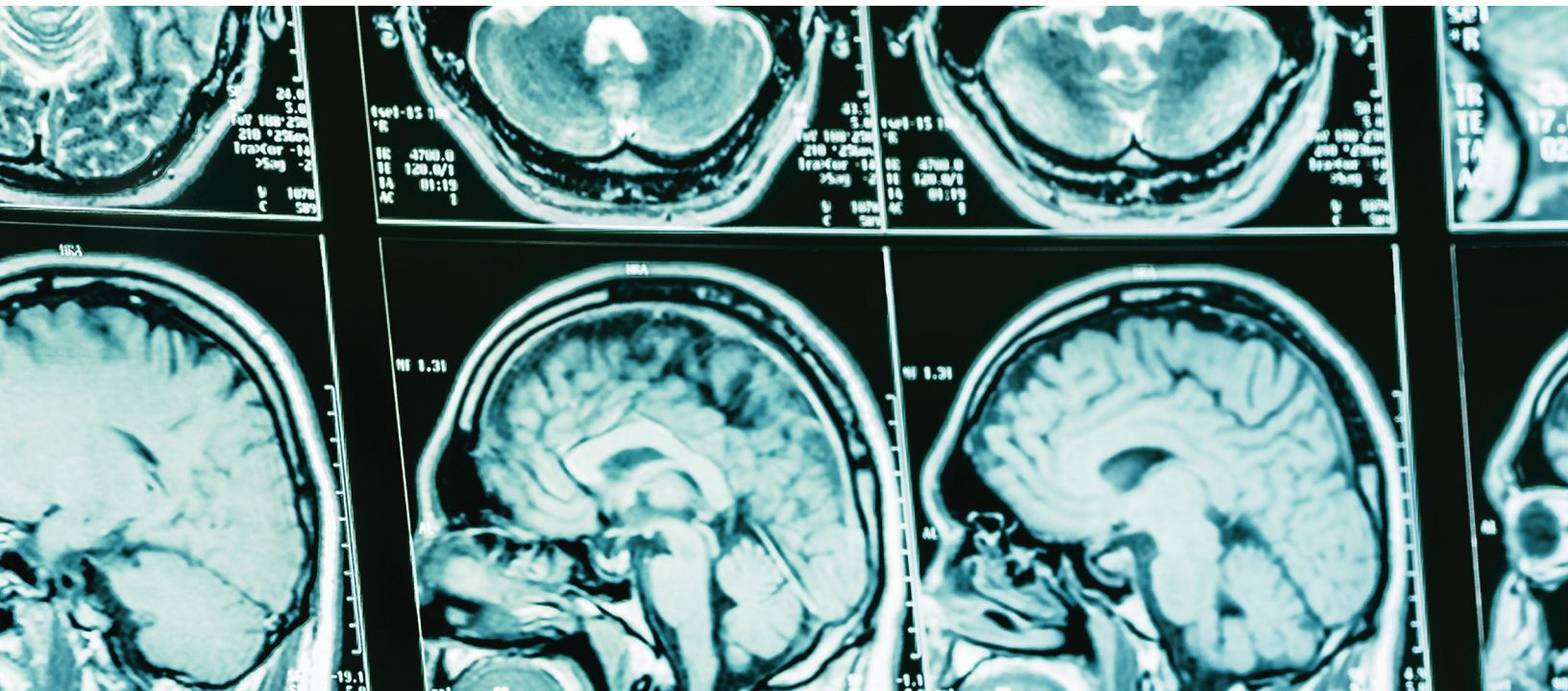
EFFECTIVENESS

STRENGTH

QUALITY

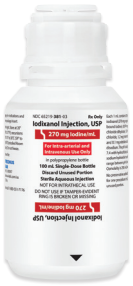
BENEFITS

To learn more about generic drugs visit **www.FDA.gov/GenericDrugs**.



Iodixanol Injection, USP

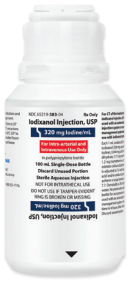
Iso-Osmolar, Dimeric Iodinated Contrast Agent[2]



NDC: 65219-381-10

Concentration: 270 mg Iodine per mL

Fill Size: 100 mL



NDC: 65219-383-10

Concentration: 320 mg Iodine per mL

Fill Size: 100 mL

NDC: 65219-381-50

Concentration: 270 mg Iodine per mL

Fill Size: 150 mL

NDC: 65219-383-50

Concentration: 320 mg Iodine per mL

Fill Size: 150 mL

NDC: 65219-383-05

Concentration: 320 mg Iodine per mL

Fill Size: 50 mL

NDC: 65219-383-70

Concentration: 320 mg Iodine per mL

Fill Size: 200 mL

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR INTRATHECAL USE

Inadvertent intrathecal administration may cause death, convulsions/seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.

Contraindications: Iodixanol Injection is contraindicated for intrathecal use.

Warnings and Precautions:

Hypersensitivity Reactions: Life-threatening or fatal reactions can occur. Most severe reactions develop shortly after the start of the injection, but reactions can occur up to hours later. Always have emergency equipment and trained personnel available.

Contrast-Induced Acute Kidney Injury: Acute injury including renal failure can occur. Minimize dose and maintain adequate hydration to minimize risk.

Cardiovascular Adverse Reactions: Life-threatening or fatal cardiovascular reactions, including hypotension, shock, and cardiac arrest have occurred with the use of Iodixanol. Most deaths occur during injection or five to ten minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest necessary dose of Iodixanol in patients with congestive heart failure.

Thromboembolic Events: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiography procedures with both ionic and nonionic contrast agents.

Extravasation and Injection Site Reactions: Extravasation of Iodixanol injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure intravascular placement of catheters prior to injection.

Thyroid Storm in Patients with Hyperthyroidism: Thyroid storm has occurred after the intravascular use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule.

Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media in patients 0 to 3 years of age. After exposure to iodinated contrast media, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

Hypertensive Crisis in Patients with Pheochromocytoma: Hypertensive crisis has occurred after the use of iodinated contrast agents in patients with pheochromocytoma. Inject the minimum amount of contrast necessary, assess the blood pressure throughout the procedure, and have measures for treatment of a hypertensive crisis readily available.

Sickle Cell Crisis in Patients with Sickle Cell Disease: Iodinated contrast agents when administered intravascularly may promote sickling in individuals who are homozygous for sickle cell disease.

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCAR) may develop from one hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS). Avoid administering iodixanol to patients with a history of a severe cutaneous adverse reaction to iodixanol.

Iodixanol Injection, USP is fully substitutable to Visipaque®.*

		Reference Listed Drug		Approved AP Generic		Therapeutically Equivalent
Name		**VISIPAQUE®[1]**		**Iodixanol Injection, USP[2]**		
Description		VISIPAQUE (iodixanol) injection is a dimeric, iso-osmolar, nonionic, water-soluble, radiographic contrast medium for intravascular (intravenous and intra-arterial) use.		Iodixanol injection, USP is a dimeric, iso-osmolar, nonionic, water-soluble, radiographic contrast medium for intravascular (intravenous and intra-arterial) use.		✓
Features		Ready-to-use sterile, pyrogen-free, and preservative free.		Ready-to-use sterile, pyrogen-free, and preservative free.		✓
Strength		Available in 2 strengths: • 270 mg of organically bound iodine per mL (550 mg Iodixanol per mL) • 320 mg of organically bound iodine per mL (652 mg Iodixanol per mL)		Available in 2 strengths: • 270 mg of organically bound iodine per mL (550 mg Iodixanol per mL) • 320 mg of organically bound iodine per mL (652 mg Iodixanol per mL)		✓
Ingredients		**Active Ingredient:** Iodixanol **Inactive Ingredients:** Calcium chloride dihydrate, sodium chloride, tromethamine, and edetate calcium disodium. Hydrochloric acid and/or sodium hydroxide for pH adjustment.		**Active Ingredient:** Iodixanol **Inactive Ingredients:** Calcium chloride dihydrate, sodium chloride, tromethamine, and edetate calcium disodium. Hydrochloric acid and/or sodium hydroxide for pH adjustment.		✓
Container		Single-dose polymer bottle		Single-dose polymer bottle		✓
Concentration		270 mg Iodine per mL	320 mg Iodine per mL	270 mg Iodine per mL	320 mg Iodine per mL	✓
Osmolality (mOsmol/kg water)		290	290	290	290	✓
Viscosity (cP)	@20°C:	12.7	26.6	12.7	26.6	✓
	@37°C:	6.3	11.8	6.3	11.8	✓
Density (g/mL)	@20°C:	1.314	1.369	1.314	1.369	✓
	@37°C:	1.303	1.356	1.303	1.356	✓
Storage		Store VISIPAQUE at controlled room temperature, 20°C to 25°C (68°F to 77°F).		Store Iodixanol injection, USP at controlled room temperature, 20°C to 25°C (68°F to 77°F).		✓

1: Visipaque Package Insert, July 2020
2: Iodixanol Injection, USP Package Insert, May 2023

*Visipaque® is a registered trademark of GE Healthcare.

Adverse Events: Serious, life-threatening, and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast agents, including Iodixanol Injection. Most common adverse reactions (incidence greater than 0.5%) in adult patients after iodixanol injection: Discomfort, warmth, pain; Cardiovascular: angina. Gastrointestinal: diarrhea, nausea, vomiting. Nervous System: agitation, anxiety, insomnia, nervousness, dizziness, headache, migraine, unusual skin sensations, sensory disturbance, fainting, sensation of spinning. Skin: itchy rash, severe itching, hives. Special Senses: Smell, taste, and vision alteration. Pediatric patients experienced similar adverse reactions.

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.

Lactation: A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk for 10 hours after iodixanol administration in order to minimize drug exposure to a breast fed infant.

Pediatric Use: Pediatric patients at high risk of adverse reactions during and after administration of contrast agents include those with asthma, hypersensitivity to other medication and/or allergens, cyanotic and acyanotic heart disease, chronic heart failure, or a serum creatinine >1.5 mg/dL. Patients with immature renal function or dehydration may be at increased risk due to prolonged elimination of iodinated contrast agents.

Geriatric Use: Dose selection for an elderly patient should be cautious usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

INDICATIONS AND USAGE

Iodixanol injection is a radiographic contrast agent indicated for the following:

Intra-arterial Procedures

Adults and pediatric patients 12 years of age and over
- Intra-arterial digital subtraction angiography (270 mg Iodine/mL and 320 mg Iodine/mL).
- Angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography (320 mg Iodine/mL).

Pediatric patients less than 12 years of age
- Angiocardiography, cerebral arteriography, and visceral arteriography (320 mg Iodine/mL).

Intravenous Procedures

Adults and pediatric patients 12 years of age and over
- Computed tomography (CT) imaging head and body (270 mg Iodine/mL and 320 mg Iodine/mL).
- Excretory urography (270 mg Iodine/mL and 320 mg Iodine/mL).
- Peripheral venography (270 mg Iodine/mL).
- Coronary computed tomography angiography (CCTA) to assist diagnostic evaluation of patients with suspected coronary artery disease (320 mg Iodine/mL).

Pediatric patients less than 12 years of age
- CT imaging of the head and body (270 mg Iodine/mL).
- Excretory urography (270 mg Iodine/mL).

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

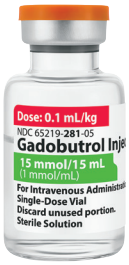
Gadobutrol Injection

Macrocyclic & High Relaxivity Gadolinium-Based Contrast Agent[3,4]

NDC: 65219-281-02

Concentration: 1 mmol per mL

Fill Size: 2 mL



NDC: 65219-281-15

Concentration: 1 mmol per mL

Fill Size: 15 mL

NDC: 65219-281-07

Concentration: 1 mmol per mL

Fill Size: 7.5 mL

NDC: 65219-287-30

Concentration: 1 mmol per mL

Fill Size: 30 mL

NDC: 65219-281-10

Concentration: 1 mmol per mL

Fill Size: 10 mL

NDC: 65219-289-65

Concentration: 1 mmol per mL

Fill Size: 65 mL

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

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

Nephrogenic Systemic Fibrosis

GBCAs increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of gadobutrol injection 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 (for example, age > 60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.**
- **For patients at highest risk for NSF, do not exceed the recommended gadobutrol injection dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.**

Contraindications: Gadobutrol Injection is contraindicated in patients with history of severe hypersensitivity reaction to Gadobutrol Injection.

Hypersensitivity Reactions: Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Gadobutrol Injection administration. Before Gadobutrol 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 Gadobutrol Injection. Administer Gadobutrol 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 brain, bone, and other organs. Linear GBCAs cause more retention than macrocyclic GBCAs. At equivalent doses, retention varies among the linear agents. Retention is lowest and similar among the macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established, but they have been established in the skin and other organs in patients with impaired renal function. 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. Consider the retention characteristics of the agent and minimize repetitive GBCA studies, when possible.

Acute Kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Gadobutrol Injection is fully substitutable to Gadavist®.*

	Reference Listed Drug						Approved AP Generic						Therapeutically Equivalent
Name	**Gadavist®[1,2]**						**Gadobutrol Injection[3,4]**						
Indication	Gadavist is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI): • To detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system in adult and pediatric patients, including term neonates • To assess the presence and extent of malignant breast disease in adult patients • To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients, including term neonates • To assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD).						Gadobutrol Injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI): • To detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system in adult and pediatric patients, including term neonates • To assess the presence and extent of malignant breast disease in adult patients • To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients, including term neonates • To assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD).						✓
Features	Sterile, clear and colorless to pale yellow solution.						Sterile, clear and colorless to pale yellow solution.						✓
Concentration	604.72 mg gadobutrol per mL (equivalent to 1 mmol gadobutrol per mL)						604.72 mg gadobutrol per mL (equivalent to 1 mmol gadobutrol per mL)						✓
Ingredients	**Active Ingredient:** gadobutrol **Inactive Ingredients:** calcobutrol sodium, trometamol, hydrochloric acid (for pH adjustment) and water for injection						**Active Ingredient:** gadobutrol **Inactive Ingredients:** calcobutrol sodium, trometamol, hydrochloric acid (for pH adjustment) and water for injection						✓
Description	Single-Dose Vials				Imaging Bulk Packages		Single-Dose Vials				Imaging Bulk Packages		✓
Fill Volume	2 mL	7.5 mL	10 mL	15 mL	30 mL	65 mL	2 mL	7.5 mL	10 mL	15 mL	30 mL	65 mL	✓
Storage	Store at 25ºC (77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].						Store at 25ºC (77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].						✓

1. Gadavist Single Dose Vial Package Insert, July 2024
2. Gadavist Imaging Bulk Package Insert, July 2024
3. Gadobutrol Injection Single Dose Vial Package Insert, September 2024
4. Gadobutrol Injection Imaging Bulk Package Insert, September 2024

Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of Gadobutrol Injection. Extravasation into tissues during Gadobutrol Injection administration may result in moderate irritation.

Overestimation of Extent of Malignant Disease in MRI of the Breast: Gadobutrol Injection MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients.

Low Sensitivity for Significant Arterial Stenosis: The performance of Gadobutrol Injection MRA for detecting arterial segments with significant stenosis (>50% renal, >70% supra-aortic) has not been shown to exceed 55%. Therefore, a negative MRA study alone should not be used to rule out significant stenosis.

Adverse Events: The most frequent (≥ 0.5%) adverse reactions associated with Gadobutrol Injection in clinical studies were headache (1.7%), nausea (1.2%) and dizziness (0.5%).

The following additional adverse reactions have been reported during postmarketing use of Gadobutrol Injection: Cardiac Arrest; Nephrogenic Systemic Fibrosis (NSF); Hypersensitivity reactions (anaphylactic shock, circulatory collapse, respiratory arrest, pulmonary edema, bronchospasm, cyanosis, oropharyngeal swelling, laryngeal edema, blood pressure increased, chest pain, angioedema, conjunctivitis, hyperhidrosis, cough, sneezing, burning sensation, and pallor); General Disorders and Administration Site Conditions: fatigue, asthenia, pain syndromes, and heterogeneous clusters of symptoms in the neurological, cutaneous, and musculoskeletal systems; Skin: Gadolinium associated plaques, Gastrointestinal Disorders: Acute pancreatitis with onset within 48 hours after GBCA administration.

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.

Pregnancy: GBCAs cross the placenta and result in fetal exposure and gadolinium retention. Because of the potential risks of gadolinium to the fetus, use Gadobutrol Injection only if imaging is essential during pregnancy and cannot be delayed.

INDICATIONS AND USAGE

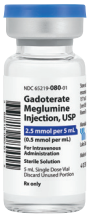
Gadobutrol Injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):
- To detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system in adult and pediatric patients, including term neonates.
- To assess the presence and extent of malignant breast disease in adult patients.
- To assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD).

Gadobutrol Injection is indicated for use in magnetic resonance angiography (MRA):
- To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients, including term neonates

This Important Safety Information does not include all the information needed to use Gadobutrol Injection safely and effectively. Please see accompanying full prescribing information, including BOXED WARNING, for Gadobutrol Injection Single Dose Vials and Imaging Bulk Package. Full prescribing information is also available at www.fresenius-kabi.com/us

Gadoterate Meglumine Injection, USP

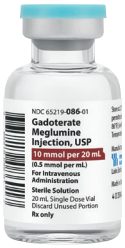
Macrocyclic & Ionic Gadolinium-Based Contrast Agent[3,4]



NDC: 65219-080-05

Concentration: 0.5 mmol per mL

Fill Size: 5 mL



NDC: 65219-086-20

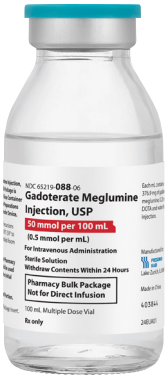
Concentration: 0.5 mmol per mL

Fill Size: 20 mL

NDC: 65219-082-10

Concentration: 0.5 mmol per mL

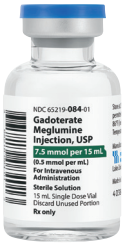
Fill Size: 10 mL



NDC: 65219-088-50

Concentration: 0.5 mmol per mL

Fill Size: 100 mL



NDC: 65219-084-15

Concentration: 0.5 mmol per mL

Fill Size: 15 mL

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

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

Nephrogenic Systemic Fibrosis

GBCAs increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of Gadoterate Meglumine Injection 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 Gadoterate Meglumine Injection dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.**

Contraindications

Gadoterate Meglumine Injection is contraindicated in patients with history of clinically important hypersensitivity reactions to Gadoterate Meglumine Injection.

Warning 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 Gadoterate Meglumine Injection have not been established with intrathecal use. Gadoterate Meglumine Injection 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 Gadoterate Meglumine Injection 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 Gadoterate Meglumine Injection, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. Monitor patients closely for need of emergency cardiorespiratory support.

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.

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

Gadoterate Meglumine Injection, USP is fully substitutable to Dotarem®*

	Reference Listed Drug					Approved AP Generic					Therapeutically Equivalent
Name	**Dotarem®[1,2]**					**Gadoterate Meglumine Injection, USP[3,4]**					
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 Single Dose Vial Package Insert, May 2024
2. Dotarem Pharmacy Bulk Package Insert, January 2024
3. Gadoterate Meglumine Injection, USP Single Dose Vial Package Insert, August 2024
4. Gadoterate Meglumine Injection, USP Pharmacy Bulk Package Insert, August 2024

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 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, convulsion, and acute pancreatitis with onset within 48 hours after GBCA administration.

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 of Gadoterate Meglumine Injection has not been established in preterm neonates. No dosage adjustment according to age is necessary in pediatric patients.

Geriatric Use: Use of Gadoterate Meglumine Injection 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 dosage adjustment is recommended for patients with renal impairment

INDICATIONS AND USAGE
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.

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 Single Dose Vials and Pharmacy Bulk Package Vials at www.fresenius-kabi.com/us.

Fresenius Kabi at a Glance

Fresenius Kabi is a global health care company that specializes in essential 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.

We are committed to putting essential medicines and technologies in the hands of health care providers. We work together to find the best answers to the challenges faced in providing quality patient care.

We leverage our 100-year history so that clinicians can deliver therapies in ways that are safe, effective and affordable.

A global team of nearly

41,000

dedicated people

Serving customers in more than

150

countries

Operating more than

90

R&D centers and manufacturing facilities worldwide

Investing More to Improve Drug Development & Supply

Fresenius Kabi is leveraging our robust supply chain and our global expertise in manufacturing and technology to develop medicines with the potential to improve patient lives.

- Operating more than 90 R&D centers and manufacturing facilities across the globe
- Nearly $1 billion invested over the past 3 years in U.S. manufacturing and distribution capabilities
- Leading manufacturing technologies
- Delivering more than 400 million units of injectable medicines delivered each year in the U.S.

For more information scan the QR code or visit **GenericContrastAgents.com**

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

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