

Gadobutrol Injection

First-to-Market Generic of Gadavist®* Providing a cost-effective MR contrast option to providers that's fully substitutable to the brand.



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.

- The risk for NSF appears highest among patients with:
 - Chronic, severe kidney disease (GFR < 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 (for example, age > 60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

Please see Important Safety Information on the following pages.

Gadobutrol Injection

Gadolinium-Based Contrast Agent

High Relaxivity, Macrocyclic Bond, High Concentration GBCA



Fresenius Kabi's Gadobutrol Injection provides you with an option that is chemically equivalent and fully substitutable to Gadavist®.* **Now you have a choice.**

Gadobutrol injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):¹

- 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 is a high relaxivity macrocyclic agent. Signal enhancement is dependent on multiple factors including concentration and relaxivity. High relaxivity may help improve tissue visualization.¹

A Cost-Effective Option from an Experienced, Reliable Supplier

Committed to Helping You

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

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. Gadobutrol Injection Package Insert, January 2023

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 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).

IMPORTANT SAFETY INFORMATION

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Fresenius Kabi's Gadobutrol Injection is fully substitutable and chemically equivalent to Gadavist®.*

	Reference Listed Drug	Approved AP Generic	Therapeutically Equivalent
Name	Gadavist® ¹	Gadobutrol Injection ²	
Indication	Gadavist is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI): <ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> 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	Single-Dose Vials	✓
Fill Volume	2 mL 7.5 mL 10 mL 15 mL	2 mL 7.5 mL 10 mL 15 mL	✓
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].	✓

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

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

1. Gadavist Package Insert, April 2022

2. Gadobutrol Injection Package Insert, January 2023

3. FDA, Generic Drug Facts Handout <https://www.fda.gov/media/107601/download>

Contraindications: History of severe hypersensitivity reaction to gadobutrol injection.

- Nephrogenic Systemic Fibrosis has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeated dosing appears to increase the risk.
- Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have occurred. Monitor patients closely during and after administration of gadobutrol injection.
- Gadolinium is retained for months or years in brain, bone, and other organs.

Adverse Events: Most common adverse reactions (incidence ≥ 0.5%) are headache, nausea, and dizziness.

Pregnancy: Use only if imaging is essential during pregnancy and cannot be delayed.

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.

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



Gadobutrol Injection

- FDA-approved, AP Rated
- High Relaxivity
- Macrocyclic Bond
- Higher Concentration GBCA
- Preservative Free
- The container closure is not made with natural rubber latex
- Bioequivalent and fully substitutable to Gadavist®*

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Unit of Sale NDC	Description	Fill Volume (mL)	Unit of Sale
65219-281-02	Single-Dose Vials	2 mL	15
65219-281-07	Single-Dose Vials	7.5 mL	20
65219-281-10	Single-Dose Vials	10 mL	20
65219-281-15	Single-Dose Vials	15 mL	20

*Gadavist® is a registered trademark of Bayer.