



**FRESENIUS
KABI**

caring for life

Iodixanol Injection, USP

First FDA-approved generic that is fully substitutable to Visipaque®.*



WARNING: NOT FOR INTRATHECAL USE

See full prescribing information for complete boxed warning

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

Please see Important Safety Information on the following pages.

Iodixanol Injection, USP

Iso-Osmolar, Dimeric Iodinated Contrast Agent

Fresenius Kabi's FDA-approved generic Iodixanol is made with quality ingredients and is safe and effective. Iodixanol provides you with an option that is chemically equivalent and fully substitutable to Visipaque®. Now you have a choice.



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

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.

Fresenius Kabi 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.**

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

IMPORTANT SAFETY INFORMATION

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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).
- Angiocardiology (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

- Angiocardiology, 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).

Fresenius Kabi's Iodixanol Injection, USP is fully substitutable and chemically equivalent to Visipaque®*

Name	Reference Listed Drug		Approved AP Generic		Therapeutically Equivalent	
	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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 Package Insert, July 2020

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Iodixanol is contraindicated for intrathecal use.

- Hypersensitivity Reactions: Life-threatening or fatal reactions can occur. 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: Hemodynamic disturbances including shock and cardiac arrest may occur during or after administration.
- Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Monitor these patients for thyroid function abnormalities and treat as clinically needed.

Adverse Events: 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 pump and discard breast milk for 10 hours after iodixanol administration.
- Geriatrics: Exercise caution in dose selection for elderly patients.

Please see package insert for full prescribing information, including BOXED WARNING, for Iodixanol Injection, USP. Full prescribing information is also available at www.fresenius-kabi.com/us.

Iodixanol Injection, USP

- Iso-Osmolar
- Dimeric
- FDA-approved, AP Rated
- Preservative Free
- Polymer Bottle
- Container is not made with natural rubber latex
- Fully substitutable and bioequivalent to Visipaque®*



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Unit of Sale NDC	Description	Concentration	Fill Size (mL)	Unit of Sale
65219-381-10	Single-Dose Polymer Bottle	270 mg iodine per mL	100 mL	10
65219-381-50	Single-Dose Polymer Bottle	270 mg iodine per mL	150 mL	10
65219-383-05	Single-Dose Polymer Bottle	320 mg iodine per mL	50 mL	10
65219-383-10	Single-Dose Polymer Bottle	320 mg iodine per mL	100 mL	10
65219-383-50	Single-Dose Polymer Bottle	320 mg iodine per mL	150 mL	10
65219-383-70	Single-Dose Polymer Bottle	320 mg iodine per mL	200 mL	10

*Visipaque® is a registered trademark of GE Healthcare.

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 Iodixanol Injection, USP. Full prescribing information is also available at www.fresenius-kabi.com/us.