FRESENIUS KABI

Iodixanol Injection, USP

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

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.

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

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.

Fresenius Kabi's Iodixanol Injection, USP is fully substitutable and chemically equivalent 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	✓
Viscosity (cP) @37°C:	6.3	11.8	6.3	11.8	✓
Density (g/mL) @20°C:	1.314	1.369	1.314	1.369	✓
Density (g/mL) @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

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.

Iodixanol Injection, USP

- **Iso-Osmolar[1]**
- **Dimeric[1]**
- **FDA-approved, AP Rated**
- **Preservative Free[1]**
- **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

1. Iodixanol Injection, USP Package Insert, May 2023

* 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.

FRESENIUS KABI

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