

Iodixanol Injection, USP

First Generic Iso-Osmolar, Dimeric Iodinated Contrast Agent



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.

Iodinated Contrast Agents

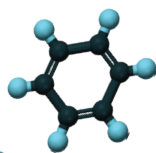
Contrast Agents should be:¹

- Easy to administer
- Non-toxic
- Stable when in use
- Concentrated in required area(s)
- Rapidly eliminated when necessary
- Non-carcinogenic
- Of appropriate viscosity for administration
- Well-tolerated by the patient
- Cost-effective

Osmolality of a solution is the measurement of the number of molecules & particles in a solution per kilogram of water.¹

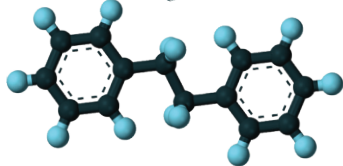
Iodine Causes Opacification

Monomer



- Monomer contrast agents have one benzene ring per molecule.
- Each benzene ring contains three iodine atoms per molecule.

Dimer



- Dimers have two benzene rings, which allow them to deliver more iodine.
- Dimers contain six iodine atoms per molecule.

Iso-Osmolar Iodinated Contrast Agents may:

- Cause less discomfort to patients upon intra-arterial administration^{2, 3, 4}
- Have fewer adverse events³
- Be a preference for vulnerable patients³

1: Requirements of 'the ideal' contrast medium and types of contrast agents. Radiology Key. <https://radiologykey.com/contrast-media-2>. Accessed 23 April. 2024.

2: McCullugh, Capasso, Patrizio, Peter. Patient Discomfort Associated with the Use of Intra-arterial Iodinated Contrast Media: A Meta-Analysis of Comparative Randomized Controlled Trials. May 24 2011; 10.1186/1471-2342-11-12

3: Widmark JM. Imaging-related medications: a class overview. *Proc (Bayl Univ Med Cent)*. 2007; 20(4): 408-17.

4: Jeffrey J. Pasternak, MD, and Eric E. Williamson, MD. Clinical Pharmacology, Uses, and Adverse Reactions of Iodinated Contrast Agents: A Primer for the Non-radiologist. (Mayo Clin.) April 2012;87(4):390-402

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

First Generic Iso-Osmolar, Dimeric Iodinated Contrast Agent

- **Iso-Osmolar⁵**
- **Dimeric⁵**
- **FDA-approved, AP Rated**
- **Preservative Free⁵**
- **Polymer Bottle**
- **Container is not made with natural rubber latex**
- **Fully substitutable and bioequivalent to Visipaque®***

*Visipaque® is a registered trademark of GE Healthcare.

Iodixanol has the lowest Osmolality of available Iodinated Contrast Agents⁶

Name	Trade Name	Classification	Osmolality (mOsm/kg)	Monomer or Dimer
Iodixanol	Visipaque®	Iso-osmolar	290	Dimer
Iohexol	Omnipaque®	Low-osmolar	322-844	Monomer
Iopromide	Ultravist®	Low-osmolar	607-774	Monomer
Ioversol	Optiray®	Low-osmolar	651-792	Monomer
Iopamidol	Isovue®	Low-osmolar	413-796	Monomer

To order the first FDA-approved generic that is fully substitutable to Visipaque®, visit: **GenericContrastAgents.com**.

5: Iodixanol Injection, USP Package Insert, May 2023
6: Individual Product Inserts

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).
 - Angiocardigraphy (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

- Angiocardigraphy, 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

Available in a range of concentrations and sizes

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

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Please see Important Safety Information on the previous pages.

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 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.**



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