



**FRESENIUS
KABI**

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Iodixanol Injection, USP

First Generic Iso-Osmolar, Dimeric Iodinated Contrast Agent



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.

Iodinated Contrast Agents

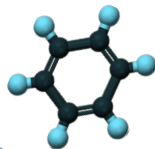
Contrast Agents should be:¹

- 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

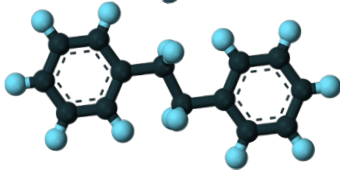
Iodine Causes Opacification

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 (radiologykey.com)

2: McCullough, Capasso, Patrizo, 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

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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).

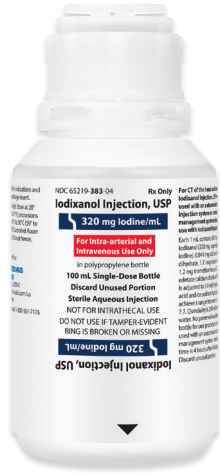
Intravenous Procedures

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).



Iodixanol Injection, USP

First Generic Iso-Osmolar, Dimeric Iodinated Contrast Agent

- 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®*

*Visipaque® is a registered trademark of GE Healthcare.

Iodixanol has the lowest Osmolality of available Iodinated Contrast Agents⁵

| 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: Individual Product Inserts

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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

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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