

Get a good look at coronary computed tomography angiography at booth #4137



Visit the GE Healthcare Life Science exhibit to virtually ‘see more’ about CCTA-enhanced with Visipaque.

Please see Product Indications and Important Risk and Safety Information about Visipaque, including Boxed Warning and Full Prescribing Information, below.

VISIPAQUE™ (IODIXANOL) INJECTION

PRODUCT INDICATIONS AND USE

Intra-Arterial Procedures

Adults and pediatric patients 12 years of age and over

- Intra-arterial digital subtraction angiography (270 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 and excretory urography (270 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 and excretory urography (270 mg Iodine/mL)

Boxed Warning and Important Risk and Safety Information About Visipaque™ (iodixanol) Injection

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.

CONTRAINDICATIONS: Visipaque Injection is contraindicated for intrathecal use. **WARNINGS AND PRECAUTIONS – Hypersensitivity Reactions:** Visipaque can cause life-threatening or fatal hypersensitivity reactions, including anaphylaxis. Most severe reactions develop shortly after the start of the injection, but reactions can occur up to hours later. Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents, and always have emergency resuscitation equipment and trained personnel available prior to Visipaque administration. Monitor all patients for hypersensitivity reactions. **Contrast-Induced Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after Visipaque administration. Use the lowest necessary dose of Visipaque in patients with renal impairment. Adequately hydrate patients prior to and following Visipaque administration. Do not use laxatives, diuretics, or preparatory dehydration prior to Visipaque administration. **Cardiovascular Adverse Reactions:** Life-threatening or fatal cardiovascular reactions, including hypotension, shock, and cardiac arrest have occurred with the use of Visipaque. 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 Visipaque in patients with congestive heart failure, and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions. **Thromboembolic Events:** Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiology procedures with both ionic and nonionic contrast agents. Use meticulous angiographic techniques, and minimize the length of the procedure. Avoid blood remaining in contact with syringes containing iodinated contrast agents. Avoid angiocardiology in patients with homocystinuria because of the risk of inducing thrombosis and embolism. **Extravasation and Injection-Site Reactions:** Extravasation of Visipaque 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. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms. **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. Evaluate the risk in such patients before use of Visipaque. **Hypertensive Crisis in Patients With Pheochromocytoma:** Hypertensive crisis has occurred after the use of iodinated contrast agents in patient with pheochromocytoma. Monitor patients when administering Visipaque if pheochromocytoma or catecholamine-secreting paragangliomas are suspected. 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. Hydrate patients prior to and following Visipaque administration, and use Visipaque only if the necessary imaging information cannot be obtained with alternative imaging modalities. **Severe Cutaneous Adverse Reactions:** Severe cutaneous adverse reactions (SCARs) 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). Reaction severity may increase and time to onset may decrease with repeat administration of contrast agents; prophylactic medications may not prevent or mitigate SCARs. Avoid administering Visipaque to patients with a history of a SCAR to Visipaque. **Pediatric Use:** Pediatric patients at high risk of adverse 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:** While no overall differences in safety or effectiveness were observed in patients >65 years, greater sensitivity regarding some older individuals cannot be ruled out. As Visipaque is substantially excreted by the kidney, the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. **Lactation:** There are no data on the presence of iodixanol in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Visipaque and any potential adverse effects on the breastfed infant from Visipaque, or from the underlying maternal condition. Interruption of breastfeeding after exposure to iodinated contrast agents is not necessary because the potential exposure of the breastfed infant to iodine is small. However, a lactating woman may consider interrupting breastfeeding, and pumping and discarding breast milk for 10 hours after Visipaque administration, to minimize drug exposure to a breastfed infant. **ADVERSE REACTIONS:** Serious, life-threatening, and fatal reactions, mostly of cardiovascular (CV) origin, have been associated with the administration of iodine-containing contrast agents, including Visipaque Injection. Most deaths occur during injection or five to 10 minutes later. Rare reports of anaphylaxis have been documented during postmarketing surveillance. As with other contrast agents, Visipaque is often associated with sensations of discomfort, warmth, or pain. The reported incidence of adverse reactions to contrast agents with a history of allergy is twice that of the general population. Patients with a history of a previous reaction to contrast agents are three times more susceptible than other patients. **DRUG INTERACTIONS – Metformin:** In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis, possibly as a result of worsening renal function. Stop metformin at the time of, or prior to, Visipaque administration in patients with an estimated glomerular filtration rate (eGFR) between 30 and 60 mL/min/1.73 m²; in patients with a history of hepatic impairment, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Reevaluate eGFR 48 hours after the imaging procedure, and reinstitute metformin only after renal function is stable. **Radioactive Iodine:** Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for six to eight weeks. **Beta-Adrenergic Blocking Agents:** The use of beta-adrenergic blocking agents lowers the threshold for and increases the severity of contrast reactions, and reduces the responsiveness of treatment of hypersensitivity reactions with epinephrine. Because of the risk of hypersensitivity reactions, use caution when administering Visipaque to patients taking beta-blockers. **Oral Cholecystographic Contrast Agents:** Renal toxicity has been reported in patients with liver dysfunction who were given an oral cholecystographic agent followed by intravascular iodinated contrast agents. Postpone the administration of Visipaque in patients who have recently received an oral cholecystographic contrast agent. **OVERDOSAGE:** The adverse effects of CM overdose may be life-threatening, affecting mainly the pulmonary and CV systems.

Prior to Visipaque administration, please [click here](#) to read the Full Prescribing Information.

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