



GE HealthCare

## Behind every image is a patient

### **Our comprehensive contrast media and injector portfolio**

is designed to meet patient and procedural needs with flexibility, safety, and efficiency across imaging modalities.

[gehealthcare.com](http://gehealthcare.com)

# A trusted leader in contrast media and imaging innovation

GE HealthCare has been a pioneer in healthcare for more than 150 years, producing over 110 million contrast media doses annually across 4 cGMP-accredited production facilities.

We are investing in long-term supply chain security with \$385 million invested over the past decade, including a new supply hub in Memphis, Tennessee, and expanded production capacity in Ireland, China, and at our API manufacturing site in Lindesnes, Norway.

GE HealthCare is working to ensure reliable access, consistent quality, and long-term support. Our heritage, global presence, and continual innovation make us a leader in precision care.

**150+**  
years

Pioneering healthcare.

**110+**  
Million doses  
annually

Produced across 4cGMP-accredited facilities worldwide.

**\$385**  
Million invested

Strengthening supply chain with new U.S. warehouse and expanded capacity in Ireland, China, and Norway.

## One comprehensive portfolio. Total confidence.

GE HealthCare delivers a comprehensive range of contrast media and injectors to support patient care across imaging modalities. Whether your needs are computed tomography, magnetic resonance, cardiac ultrasound, or molecular imaging, our portfolio is built for safety, flexibility, and workflow efficiency.

This depth of offering allows providers to reduce inventory burden, streamline workflows, and ensure the right agent for the right patient at the right time.



### Magnetic Resonance (MR)

Intelligent imaging devices and software solutions, designed to improve clinical decisions, imaging operations, and exam workflow efficiency.



### Ultrasound

GE HealthCare supports you with distinct ultrasound systems as specialized as the care you provide.



### Computed Tomography (CT)

Our family of innovative CT products let you match a system to your exact imaging needs.



### Molecular Imaging (MI)

Our molecular imaging systems are designed and built to generate insightful images with the sensitivity to capture each patient's unique inside story.

# Trusted agents for your most critical imaging needs

## Omnipaque™ (iohexol) injection

- Broad indications: IV, oral, intrathecal, intra-arterial, and more for use across a broad range of body imaging
- Patients prefer the neutral taste over traditional agents<sup>1</sup>
- Shatterproof +PLUSPACK polymer bottle



**1st AND ONLY**

low-osmolar contrast approved for oral use in the U.S.

## Visipaque™ (iodixanol) injection

- Iso-osmolar and isotonic formulation
- Indicated for multiple intra-arterial and intravenous procedures
- Formulated for at risk patient populations



May help **mitigate MARCE** and **improve patient comfort**<sup>2,3</sup>

## Clariscan™ (gadoterate meglumine) injection for intravenous use

- Macrocyclic, ionic agent used to enhance visualization in MR procedures across a range of indications
- Multiple packaging formats



**20+ MILLION**

doses globally with excellent tolerability<sup>4,5</sup>

# Safe. Efficient. Ready when you are.

## Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

- Enhances left ventricle visualization in suboptimal echocardiograms and helps to improve the delineation of the left ventricular endocardial borders
- No reconstitution or vial mixer required
- Stable at room temperature for up to 24 hours



**THE ONLY**

PEG-free ultrasound enhancing agent

**NOW FDA APPROVED**

for pediatric echocardiograms

# Speed, savings, and simplicity at your fingertips

## CT motion™

- Syringeless system saves up to 90 minutes per CT suite daily<sup>6\*</sup>
- Reduces contrast waste using multi-dose bottles with continuous loop design<sup>7</sup>
- Bluetooth-enabled
- Hygienic closed system



## Max 3™

- Wireless and Wi-Fi enabled for MR and PET MR examinations
- Toggle between contrast agents to optimize use
- Safety-first design with automated air detection and SafeConnect™



Perform up to **6 more scans** per day<sup>6\*</sup>



approved use of multidose consumables<sup>\*\*</sup>

\*Results are unique to University of Washington's clinical trial and may not be extrapolated or generalized to other settings.

\*\* Not all consumables are multidose.

# Reducing waste. Increasing productivity.

CT motion™, a multi-use syringeless injector (MUSI), offered an 84.6% reduction in plastic waste when compared to a single-use syringe injector (SUSI)<sup>7\*</sup>

**3,351 lbs**

Annual plastic waste while using a single-use syringe injector<sup>\*\*</sup>



**10x hospital beds<sup>†</sup>**



<sup>†</sup> Based on average weight of a hospital bed - 331 lbs (150 kg)

Main contributors to plastic waste included ICM bottles, saline bags, packaging, patient lines, tubing, and syringes.<sup>7</sup>

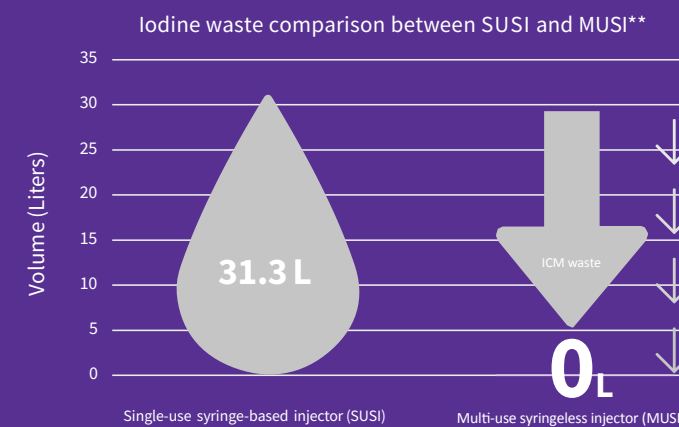
<sup>\*\*</sup>Over a 16-week period the SUSI model estimated 467.7 kg (1,031.10 lb) plastic waste compared to the MUSI model of 71.9 kg (158.51 lb) plastic waste.<sup>7</sup>

The estimated potential **cost savings** of plastic waste reduction over a 16-week period amounted to \$7,200 or **\$23,400 annually.**<sup>7</sup>



Results are unique to UW Madison's analysis and may not be extrapolated or generalized to other settings.

CT motion demonstrated a **complete elimination of iodinated contrast media waste** when compared to a single-use syringe injector<sup>7</sup>



<sup>\*\*\*</sup>1,444 contrast-enhanced CT exams were performed using each injector over a 16-week period in this observational study. Patients weights for 25th/50th/75th percentiles were 152/183/224 kg, contrast volumes for 25th/50th/75th percentiles were 85/100/116 mL. The study did not include (or provide) age or gender information.<sup>7</sup>

# Experience the full range of contrast solutions

Looking through a patient-focused lens is always a priority. Since each patient is unique, our contrast media portfolio includes a variety of proprietary branded agents and FDA-approved generics tailored for different imaging techniques to enhance precision, minimize risk, and optimize outcomes.

With GE HealthCare, you have reliable access to contrast media you are familiar with, combined with decades of experience and controlling end-to-end production for all our products from a cGMP-accredited manufacturer you know and can trust.

**Clariscan™**  
(gadoterate meglumine)  
injection for intravenous use

A generic, cost-effective macrocyclic ionic MRI contrast agent and is one of the most used molecules on the market globally, backed by over 30 years of use



Product	Order size	SKU	NDC
2.5 mmol per 5 mL glass vial	Packs of 10	C105	0407-2943-06
5 mmol per 10 mL glass vial	Packs of 10	C110	0407-2943-01
7.5 mmol per 15 mL glass vial	Packs of 10	C115	0407-2943-02
10 mmol per 20 mL glass vial	Packs of 10	C120	0407-2943-05
50 mmol per 100 mL plastic bottle	Packs of 10	C300	0407-2943-70
5 mmol per 10 mL Single-Dose Plastic Syringe	Packs of 10	C210	0407-2943-12
7.5 mmol per 15 mL Single-Dose Plastic Syringe	Packs of 10	C215	0407-2943-17
10 mmol per 20 mL Single-Dose Plastic Syringe	Packs of 10	C220	0407-2943-22

**OMNIPAQUE™**  
(IOHEXOL) INJECTION

Providing reliability and choice, this low-osmolar iodinated contrast medium is indicated for intravenous, intra-arterial, intrathecal, intra-articular, body cavity, oral and rectal use



Product	Order size	SKU	NDC
50 mL of 140 mg I/mL	Packs of 10	Y-510	0407-1401-52
10-mL vial of 180 mg I/mL	Packs of 10	Y-101	0407-1411-10
50 mL of 240 mg I/mL	Packs of 10	Y-520	0407-1412-30
100 mL of 240 mg I/mL	Packs of 10	Y-522	0407-1412-33
10-mL bottle of 240 mg I/mL	Packs of 10	Y-203	0407-1412-10
20-mL bottle of 240 mg I/mL	Packs of 10	Y-220	0407-1412-20
10-mL bottle of 300 mg I/mL	Packs of 10	Y-306	0407-1413-10
mL of 300 mg I/mL in 50-mL container	Packs of 10	Y-503	0407-1413-59
50 mL of 300 mg I/mL	Packs of 10	Y-530	0407-1413-61
100 mL of 300 mg I/mL	Packs of 10	Y-532	0407-1413-63
150 mL of 300 mg I/mL	Packs of 10	Y-534	0407-1413-65
50 mL of 350 mg I/mL	Packs of 10	Y-540	0407-1414-89
75 mL of 350 mg I/mL	Packs of 10	Y-541	0407-1414-90
100 mL of 350 mg I/mL	Packs of 10	Y-542	0407-1414-91
150 mL of 350 mg I/mL	Packs of 10	Y-544	0407-1414-93
200 mL of 350 mg I/mL	Packs of 10	Y-546	0407-1414-94
500 mL of 300 mg I/mL (Imaging Bulk Package*)	Packs of 10	Y-538I	0407-1413-72
500 mL of 350 mg I/mL (Imaging Bulk Package*)	Packs of 10	Y-548I	0407-1414-72
500 mL of 9 mg I/mL (oral use)	Packs of 10	RTD-09	0407-1415-09
500 mL of 12 mg I/mL (oral use)	Packs of 10	RTD-12	0407-1416-12

\* Omnipaque Imaging Bulk Package (IBP) is indicated for CT of the head and body in adults (300 mg I/mL, 350 mg I/mL) and pediatric (300 mg I/mL). IBP is for use only with an automated contrast injection system, contrast management system, or contrast media transfer set cleared for use with Omnipaque IBP.

**OPTISON™**  
(Perflutren Protein-Type A Microspheres  
Injectable Suspension, USP)

Used to opacify the left ventricle and improve delineation of the left ventricular endocardial borders, Optison is the only ultrasound enhancing agent in the US without polyethylene glycol (PEG)



Product	Order size	SKU	NDC
OPTISON 3 ml   5 vials	Packs of 5	1173653	00407-2707-03
OPTISON 3 ml   18 vials	Packs of 18	1182095	00407-2707-18
OPTISON Optispike	Packs of 20	1186905	00000-2710-21

**VISIPAQUE™**  
(IODIXANOL) INJECTION

Formulated for at risk patient populations, this iodinated contrast medium for intravascular use is iso-osmolar to blood and isotonic at all concentrations available in the US



Product	Order size	SKU	NDC
VISIPAQUE 270mg/ml USB 10x50 mL USA	Packs of 10	V-550	0407-2222-16
VISIPAQUE 270mg/ml USB 10x100 mL USA	Packs of 10	V-552	0407-2222-17
VISIPAQUE 270mg/ml USB 10x150 mL USA	Packs of 10	V-554	0407-2222-19
VISIPAQUE 270mg/ml USB 10x200 mL USA	Packs of 10	V-556	0407-2222-21
VISIPAQUE 320mg/ml USB 10x50 mL USA	Packs of 10	V-560	0407-2223-16
VISIPAQUE 320mg/ml USB 10x100 mL USA	Packs of 10	V-562	0407-2223-17
VISIPAQUE 320mg/ml USB 10x150 mL USA	Packs of 10	V-564	0407-2223-19
VISIPAQUE 320mg/ml USB 10x200 mL USA	Packs of 10	V-566	0407-2223-21
VISIPAQUE 320mg/ml USB PBP 10x500 mL USA	Packs of 10	V-568B	0407-2223-23

# Built for the future of imaging

At GE HealthCare, our contrast media injector portfolio is backed by leading environmental sustainability programs, an experienced clinical support team, and ongoing investments in our supply chain and quality manufacturing facilities.



+PLUSPAK™ 100% recyclable packaging reduces carbon footprint



No cost iodine recycling programs are active in the U.S., Canada, and 11 European countries



Highly skilled clinical sales team with many years of hands-on patient care experience



Investments in global supply infrastructure ensure continuous availability



End-to-end GE HealthCare-owned manufacturing for consistent quality

**OMNIPAQUE™ (iohexol) injection, HCP Important Safety Information**

**WARNING: RISKS ASSOCIATED WITH INTRATHECAL ADMINISTRATION OF OMNIPAQUE INJECTION 140 mg IODINE/mL and 350 mg IODINE/mL**

**Use only the OMNIPAQUE iodine concentrations and presentations recommended for intrathecal procedure. Intrathecal administration of OMNIPAQUE of a wrong iodine concentration, even if inadvertent, may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.**

**INDICATIONS:**

OMNIPAQUE is indicated for intrathecal procedures for:

- Myelography and computerized tomography myelography (lumbar, thoracic, cervical, total columnar) in adults and pediatric patients aged 2 weeks and older
- CT cisternography in adults and pediatric patients aged 2 weeks and older

OMNIPAQUE is indicated for intra-arterial procedures for:

- Cardiac ventriculography in adults and pediatric patients
- Aortography including studies of aorta and its branches in adults and pediatric patients
- Selective coronary arteriography in adults
- Cerebral arteriography in adults
- Peripheral arteriography in adults
- Intra-arterial digital subtraction angiography (IA-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults
- Pulmonary angiography in pediatric patients

OMNIPAQUE is indicated for intravenous procedures for:

- Excretory urography in adults and pediatric patients
- CT of the head and body in adults and pediatric patients
- Peripheral venography (phlebography) in adults
- Intravenous digital subtraction angiography (IV-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults

OMNIPAQUE is indicated for oral or rectal procedures for:

- Radiographic examination of the gastrointestinal tract in adults and pediatric patients
- CT of the abdomen and pelvis in conjunction with intravenous administration of OMNIPAQUE in adults and pediatric patients

OMNIPAQUE is indicated for intraarticular procedures for:

- Arthrography in adults

OMNIPAQUE is indicated for body cavity procedures for:

- Endoscopic retrograde pancreatography and cholangiopancreatography in adults
- Herniography in adults
- Hysterosalpingography in adults
- Voiding cystourethrography in pediatric patients

Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure. See dosing and administration in the prescribing information.

**CONTRAINDICATIONS:**

OMNIPAQUE for hysterosalpingography is contraindicated during pregnancy or suspected pregnancy, menstruation or when menstruation is imminent, within 6 months after termination of pregnancy, within 30 days after conization or curettage, when signs of infection are present in any portion of the genital tract including the external genitalia, and when reproductive tract neoplasia is known or suspected because of the risk of peritoneal spread of neoplasm.

**WARNINGS AND PRECAUTIONS:**

**Risks Associated with Intrathecal Administration of OMNIPAQUE injection 140 mg iodine/mL and 350mg iodine/mL:** Use only the iodine concentrations and presentations recommended for intrathecal procedures. **See Boxed Warning**

**Risks Associated with Parenteral Administration of OMNIPAQUE Oral Solution:** UUse for oral use only. Adverse reactions such as hemolysis may occur if OMNIPAQUE is administered intravenously or intraarterially due to low osmolality.

**Hypersensitivity Reactions:** OMNIPAQUE can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk in patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity.

**Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration.

**Cardiovascular Adverse Reactions:** Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available.

**Thromboembolic Events:** Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiology procedures with iodinated contrast agents. Risk factors for thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications. Use meticulous angiographic techniques and minimize length of procedures to minimize events. Avoid blood remaining in contact with syringes containing OMNIPAQUE and avoid angiocardiology in patients with homocystinuria.

**Extravasation and Injection Site Reactions:** Extravasation of OMNIPAQUE during intravenous or intra-arterial injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure correct placement and monitor patients for extravasation.

**Thyroid Storm in Patients with Hyperthyroidism:** Thyroid storm has occurred after the intravenous or intra-arterial use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule. Evaluate the risk in these patients before use of OMNIPAQUE.

**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.

**Hypertensive Crisis in Patients with Pheochromocytoma:** Hypertensive crisis has occurred after the use of iodinated contrast agents in patients with pheochromocytoma. Monitor patients when administering OMNIPAQUE intravenously or intra-arterially. Use the minimum amount of contrast necessary and monitor blood pressure throughout the procedure.

**Sickle Cell Crisis in Patients with Sickle Cell Disease:** Iodinated contrast agents when administered intravenously or intra-arterially may promote sickling in individuals who have sickle cell disease. Hydrate patient prior to and following OMNIPAQUE administration and use OMNIPAQUE only if the necessary imaging cannot be obtained with alternative imaging modalities.

**Severe Cutaneous Adverse Reactions:** Severe cutaneous adverse reactions may develop from 1 hour to several weeks after intravenous or intra-arterial contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis, acute generalized exanthematous pustulosis and drug reaction with eosinophilia and systemic symptoms. Reaction severity may increase and time to onset may decrease with repeat administration of contrast agents. Prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering to patients with a history of severe cutaneous reactions.

**Interference with Laboratory Test:** OMNIPAQUE can interfere with protein-bound iodine test.

**Increased Risk of Seizures with Intrathecal Procedures:** Focal and generalized motor seizures have been reported after intrathecal use of iodinated contrast agents. Use of medications that may lower the seizure threshold should be carefully evaluated. Consider discontinuing these agents at least 48 hours before and at least 24 hours following intrathecal administration of OMNIPAQUE.

**Most Common Adverse Reactions**

**Intrathecal Administration:** In clinical trials ≥1% of 1,531 adult patients included: headaches, pain (including backache, neckache, stiffness, and neuralgia), nausea, vomiting and dizziness. In clinical trials ≥1% of 152 pediatric patients included headache, vomiting and backache.

**Intra-arterial or Intravenous Administration:** In clinical trials ≥1% of 1,485 adult patients included arrhythmias (including PVCs and PACs), pain, vision abnormalities (including blurred vision and photomas), taste perversion and nausea. In clinical trials ≥1% of 391 pediatric patients included vomiting and nausea.

**Oral or Rectal Administration for Examination of the Gastrointestinal Tract:** In clinical trials ≥1% of 54 adult patients included diarrhea, nausea, vomiting, abdominal pain, flatulence and headache. In clinical trials of 58 pediatric patients included diarrhea, vomiting, nausea, abdominal pain, fever, urticaria and hypotension.

**Intraarticular Administration:** In clinical trials ≥1% of 285 adult patients included administration site pain, swelling and heat.

**Body Cavity Use:** No new adverse reactions were associated with the use of OMNIPAQUE in 51 pediatric patients.

**Drug-Drug Interactions:**

In patients with renal impairment, metformin can cause lactic acidosis.

OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE.

**Pregnancy and Lactation:**

There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth.

Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.

Please scan the QR code to see the full Prescribing Information, including boxed warning and additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.



**OMNIPAQUE™**  
(IOHEXOL) INJECTION

**INDICATIONS AND USE – VISIPAQUE™ (IODIXANOL)**

**Intra-Arterial Procedures**

**Adult and pediatric patients 12 years of age and older:** 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**

**Adult and pediatric patients 12 years of age and older:** Computed tomography (CT) imaging of the head and body (270 and 320 mg iodine/mL); excretory urography (270 and 320 mg iodine/mL); peripheral venography (270 mg iodine/mL); coronary computed tomography angiography (CCTA) to assist in the 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)

**IMPORTANT SAFETY INFORMATION FOR VISIPAQUE (iodixanol) INJECTION**

**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.**

**CONTRAINDICATION:**

Visipaque 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 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.
- **Thromboembolic Events:** Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiology procedures with both ionic and nonionic contrast agents.
- **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.
- **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 (ICM) in patients 0 to 3 years of age.
- **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.

Continued on next page >

• **Severe Cutaneous Adverse Reactions (SCAR):** 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 Visipaque to patients with a history of a SCAR to Visipaque.

**USE IN SPECIFIC POPULATIONS:**

- **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:** While no overall differences in safety or effectiveness were observed in patients >65 years, greater sensitivity regarding some older individuals cannot be ruled out.

**ADVERSE REACTIONS:**

- Serious, life-threatening, and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast agents, including Visipaque Injection.
- Most common adverse reactions (incidence greater than 0.5%) in adult patients after Visipaque 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.

**DRUG-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 eGFR between 30 and 60 mL/min/1.73 m<sup>2</sup>; in patients with a history of hepatic impairment, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate 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 6 to 8 weeks.
- **Beta-adrenergic Blocking Agents:** The use of beta-adrenergic blocking agents lowers the threshold for and increases the severity of contrast reactions and 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 agent.

Please scan the QR code to see the full Prescribing Information, including boxed warning and additional Important Safety Information.



To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

**VISIPAQUE™**  
(IODIXANOL) INJECTION

**IMPORTANT SAFETY INFORMATION ABOUT CLARISCAN™ (GADOTERATE MEGGLUMINE)**

**PRODUCT INDICATIONS AND USE**

Clariscan™ (gadoterate meglumine) is a prescription gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

**WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS (NSF)**

**Risk Associated with Intrathecal Use**  
**Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. Clariscan is not approved for intrathecal use.**

**Nephrogenic Systemic Fibrosis**  
**GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of Clariscan in these patients unless the diagnostic information is essential and not available with non- contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.**

**The risk for NSF appears highest among patients with:**

- **Chronic, severe kidney disease (GFR < 30 mL/min/1.73m<sup>2</sup>), or**
- **Acute kidney injury.**

**Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g., age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.**

**For patients at highest risk for NSF, do not exceed the recommended Clariscan dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.**

**CONTRAINDICATIONS:**

History of clinically important hypersensitivity reactions to Clariscan.

**WARNINGS AND PRECAUTIONS:**

- **Risk Associated with Intrathecal Use:** Intrathecal administration of GBCAs can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of Clariscan have not been established with intrathecal use. Clariscan is not approved for intrathecal use.
- **Nephrogenic Systemic Fibrosis:** GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of Clariscan among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.
- **Hypersensitivity Reactions:** Anaphylactic and anaphylactoid reactions have been reported with Clariscan, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died.
- Before Clariscan administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Clariscan.
- **Gadolinium Retention:** Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver and spleen). While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.
- **Acute Kidney Injury:** In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging.
- **Extravasation and Injection Site Reactions:** Ensure catheter and venous patency before the injection of Clariscan. Extravasation into tissues during Clariscan administration may result in tissue irritation.

**ADVERSE REACTIONS:**

- In clinical trials, the most frequent adverse reactions that occurred in > 0.2% of patients who received Clariscan included: nausea, headache, injection site pain, injection site coldness and rash.
- Serious adverse reactions in the postmarketing experience have been reported with Clariscan. Serious adverse reactions include but are not limited to arrhythmia, cardiac arrest, respiratory arrest, pharyngeal edema, laryngospasm, bronchospasm, coma, convulsion and acute pancreatitis with onset within 48 hours post GBCA administration.

**USE IN SPECIFIC POPULATIONS:**

- **Pregnancy:** GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. Use only if imaging is essential during pregnancy and cannot be delayed.
- **Lactation:** There are no data on the presence of gadoterate in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is present in breast milk.
- **Pediatric Use:** The safety of Clariscan has not been established in preterm neonates. No dosage adjustment according to age is necessary in pediatric patients.
- **Geriatric Use:** The use of Clariscan in elderly patients should be cautious, reflecting the greater frequency of impaired renal function and concomitant disease or other drug therapy. No age-related dosage adjustment is necessary.
- **Renal Impairment:** No Clariscan dosage adjustment is recommended for patients with renal impairment.

Please scan the QR code to see Clariscan full Prescribing Information, including the Medication Guide, for additional important safety information.



To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

**Clariscan™**  
(gadoterate meglumine)  
injection for intravenous use

**OPTISON™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)**

**INDICATIONS**

OPTISON is an ultrasound contrast agent indicated for use in adult and pediatric patients with suboptimal echocardiogram to opacify to the left ventricle to improve the delineation of the left ventricle endocardial borders.

**WARNING: SERIOUS CARDIOPULMONARY REACTIONS**  
**Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration**

- **Assess all patients for the presence of any condition that precludes OPTISON administration**
- **Always have resuscitation equipment and trained personnel readily available**

**CONTRAINDICATIONS:**

OPTISON is contraindicated in patients with known or suspected hypersensitivity to perflutren or albumin.

**WARNINGS AND PRECAUTIONS:**

- Serious cardiopulmonary reactions including fatalities have occurred uncommonly during or shortly following perflutren-containing microsphere

administration, typically within 30 minutes of administration. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias).

- Serious anaphylactic reactions have been observed during or shortly following perflutren-containing microsphere administration, including shock, hypersensitivity, bronchospasm, throat tightness, angioedema, edema (pharyngeal, palatal, mouth, peripheral, localized), swelling (face, eye, lip, tongue, upper airway), facial hypoesthesia, rash, urticaria, pruritus, flushing, and erythema have occurred in patients with no prior exposure to perflutren-containing microsphere products.
- When administering OPTISON to patients with a cardiac shunt, microspheres can bypass filtering of the lungs and enter the arterial circulation. Assess patients with shunts for embolic phenomena following OPTISON administration. OPTISON is only for intravenous administration; do not administer OPTISON by intra-arterial injection.
- High ultrasound mechanical index values may cause microsphere rupture and lead to ventricular arrhythmias. Additionally, end-systolic triggering with high mechanical indices has been reported to cause ventricular arrhythmias. OPTISON is not recommended for use at mechanical indices greater than 0.8.

**ADVERSE REACTIONS:**

Common adverse reactions (incidence > 0.5%) were: headache, nausea and/or vomiting, warm sensation or flushing, dizziness, dysgeusia, chills or fever, flu-like symptoms, malaise/weakness/fatigue, chest pain, dyspnea, injection site discomfort, and erythema. Cardiac arrests and other serious but nonfatal adverse reactions were uncommonly reported in post-approval use. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions. Overall, the safety profile observed in pediatric patients from the clinical study was consistent with the safety profile in adult patients.

**USE IN SPECIFIC POPULATIONS:**

**Pregnancy and Lactation:**

There are no data with OPTISON use in pregnant woman to inform any drug-associated risks. There are no data on the presence of perflutren protein-type A microspheres in human milk, the effects on the breastfed infant or the effects on milk production.

**Pediatric Use:**

Safety and efficacy of OPTISON in pediatric patient is supported by evidence from adequate and well-controlled studies in adults and additional efficacy and safety data from a clinical study in 37 pediatric patients aged 9-17 years.

**Geriatric Use:**

No overall differences in safety or effectiveness were observed in patients 65 years and over but a greater sensitivity to OPTISON in older individuals cannot be ruled out.



Please scan the QR code to see the full Prescribing Information, including boxed warning and additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

**OPTISON™**  
(Perflutren Protein-Type A Microspheres  
Injectable Suspension, USP)



# Together, let's enable **confident imaging decisions**

From individual product benefits to workflow support enabled by a comprehensive portfolio, GE HealthCare brings the depth of offerings and the reliability of a trusted global leader. Let's work together to enable better patient care, streamline operations, and meet your imaging needs with confidence.



Talk to your GE HealthCare representative or scan the QR code to visit our website [gehealthcare.com/products/contrast-media](https://www.gehealthcare.com/products/contrast-media) to learn more.

1. Parakh A et al. Low-keV and Low-kVp CT for Positive Oral Contrast Media in Patients with Cancer: A Randomized Clinical Trial. *Radiology*. 2019; 291(3): 620-29.
2. McCullough P et al. Major Adverse Renal and Cardiovascular Events following Intra-Arterial Contrast Media Administration in Hospitalized Patients with Comorbid Conditions. *Cardiorenal Med* 2021; 11(4): 193-9.
3. Almén T. Visipaque – a step forward a historical review *Acta Radiol*. 1995; 36(Suppl.399): 2-18.
4. GE HealthCare Data on File, Safety Profile Clariscan March 2023.
5. Clariscan [prescribing information]. Marlborough, MA GE HealthCare; 2020.
6. Mattinson T, et al. Improving CT workflow and in a busy subspecialty emergency room using a novel power injector technology. In *RSNA*; Nov 27- Dec 1 2022; Chicago.
7. Toia G, et al. Consumable Material Waste and Workflow Efficiency Comparison Between Multi-use Syringeless and Single-use Syringe-Based Injectors in Computed Tomography, *Acad Radiol*. 2023 Oct;30(10):2340-2349. doi: 10.1016/j.acra.2023.05.038