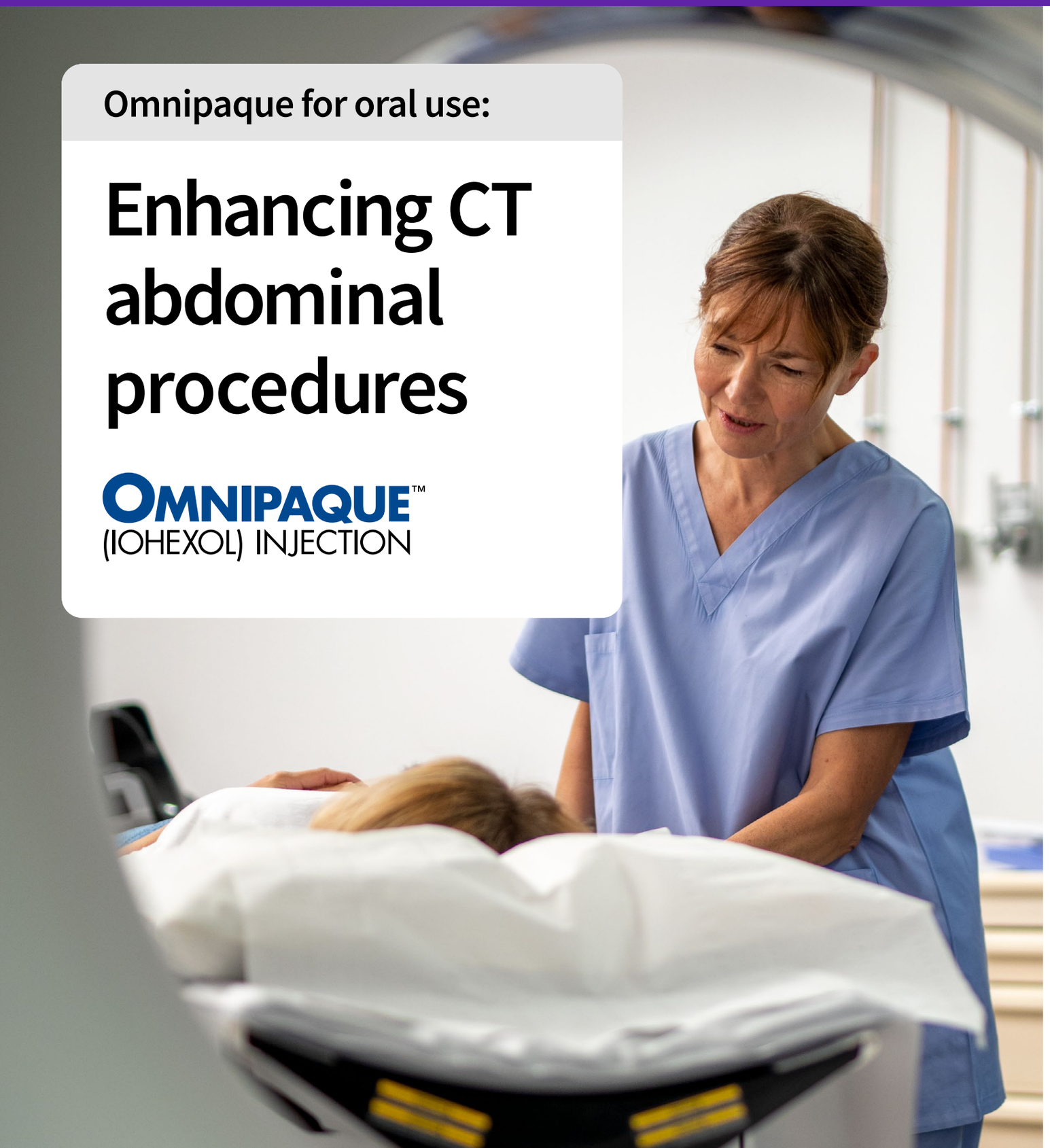
GE HealthCare



Omnipaque for oral use:

Enhancing CT abdominal procedures

OMNIPAQUE™
(IOHEXOL) INJECTION

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.

Please see additional Important Safety Information on the following pages, and Full Prescribing Information, including Boxed Warning, here, for additional important safety information.

This communication is for digital use only.

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:** Use 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-threating 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 angiocardiography 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 angiocardiography 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.

(Continued on next screen)

- **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 my 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.

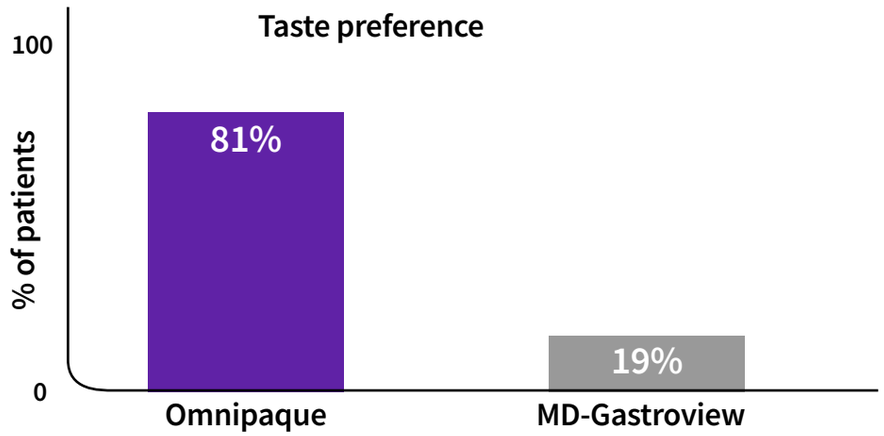
Please see full Prescribing Information, including Boxed Warning, here, for additional Important Safety Information.

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.

Patient experience

A neutral taste for your patients[1]

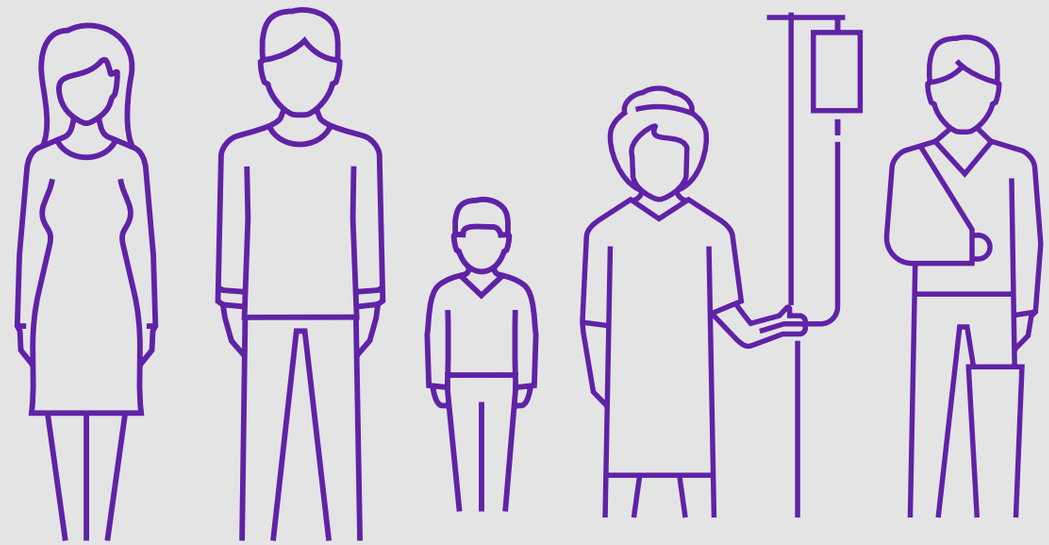
- Patients in an abdominal computed tomography study drank the entire prescribed amount and said they would do so again, if necessary[2]
- Shown to have a neutral taste when compared with ionic Gastrografin® (diatrizoate meglumine and diatrizoate sodium solution USP)[1]
- Omnipaque received a significantly better taste preference score than did MD-Gastroview® (diatrizoate meglumine and diatrizoate sodium solution USP) (*P*<0.001)[3]



Omnipaque Oral Solution supports patient safety

Examples of patient considerations[4]

- Suspected bowel perforation or bowel obstruction
- Aspiration risk
- Patients with cancer[4]



Gastrografin is a registered trademark of Bracco Diagnostics Inc.
MD-Gastroview is a registered trademark of Guerbet LLC.

IMPORTANT SAFETY INFORMATION

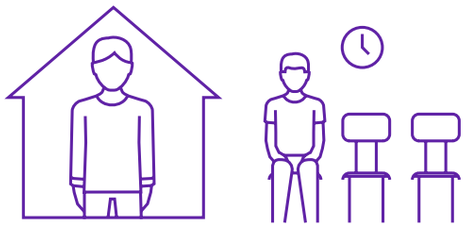
WARNINGS AND PRECAUTIONS

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.

Please see additional Important Safety Information here, and Full Prescribing Information, including Boxed Warning, here.

OMNIPAQUE™
(IOHEXOL) INJECTION

Cup-to-table time is important in every patient setting

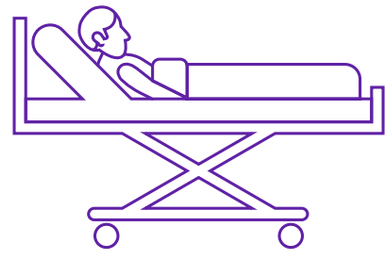


Outpatient setting

Easily identifiable label allows patients to clearly understand administration while also allowing staff to provide minimal instructions to patients for consumption.

Inpatient setting

Supports optimization of workflow by eliminating dilution procedures.



Emergency department

Can reduce wait time associated with ordering positive contrast. Cup-to-table time potentially reduced.

Workflow efficiency

Helps simplify the process of preparing your patients for diagnostic procedures when using prediluted solution and precise dose concentration

Ready-to-drink formulation

No dilution step needed[5]

Minimize process to mix oral contrast:

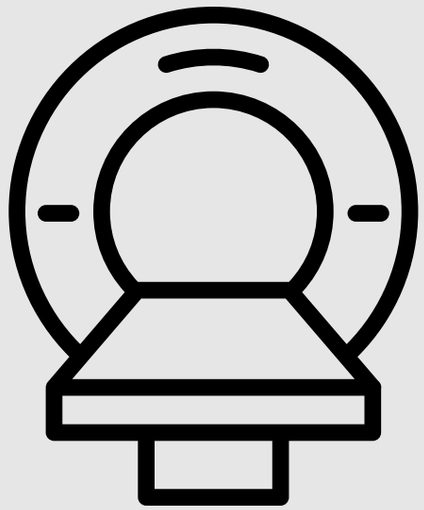
- No additional labeling
- No additional containers
- No additional steps or processes to obtain supplies to dilute
- No complex instructions for patients to consume solution

Please see additional Important Safety Information here, and Full Prescribing Information, including Boxed Warning, here.

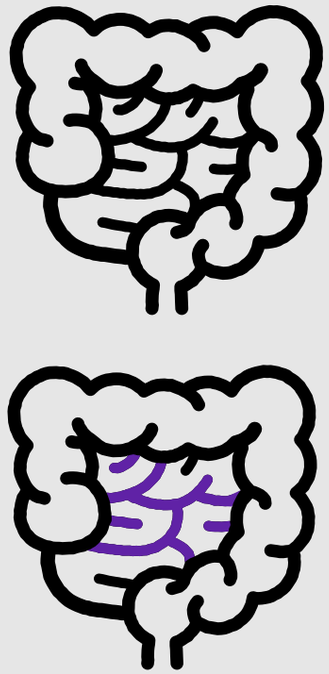
OMNIPAQUE™ (IOHEXOL) INJECTION

Evidence supports use of positive vs neutral oral contrast for malignant deposits on abdominal CT[6]

265 oncology patients with available CT before intra-abdominal malignant deposits were found on later CT.



Among the earlier scans, **100** used positive oral agent and **165** used neutral oral agent.



Positive oral contrast was associated with higher negative predictive value (NPV) than neutral oral contrast:

NPV: 65.8% for positive agent with adequate bowel filling

NPV: 45.2% for positive agent with inadequate bowel filling

NPV: 35.2% for neutral agent

Adequate bowel filling with positive oral contrast agent may improve detection of intra-abdominal malignant deposits

INDICATIONS:

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 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 (IVDSA) of the head, neck, abdominal, renal, and peripheral vessels in adults

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

Please see additional Important Safety Information here, and Full Prescribing Information, including Boxed Warning, here.

OMNIPAQUE™ (IOHEXOL) INJECTION

We're investing, from extraction to injection, to secure future iodinated contrast media supply[7]

- GE HealthCare has invested **$385M** over the last decade to increase capacity and support the growing iodinated contrast media market
- GE HealthCare announced multi-year agreement with Sociedad Quimica y Minera (SQM) to **secure iodine supply** for contrast media
- In November 2022, GE HealthCare announced an **$80 million** investment to expand contrast media production capacity
- In 2025, GE HealthCare invested **$138 million** in Cork, Ireland manufacturing facility[8]

Extraction >> Injection

1

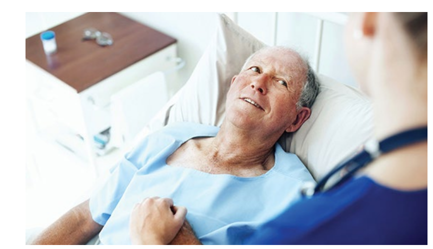
Extraction and processing of iodine:
We're securing and protecting long-term supply

2

Production of API: Lindesnes, Norway—
We're producing more API for more contrast media

3

Fill and finish: Cork, Oslo, Shanghai—
We're producing ~30% more patient doses by 2025[7]



4

Extraction and processing of iodine:
We're securing and protecting long-term supply

Please see additional Important Safety Information here, and Full Prescribing Information, including Boxed Warning, here.

OMNIPAQUE™ (IOHEXOL) INJECTION

GE HealthCare

We have full stock availability and secure, consistent supply to support your needs!

An FDA-approved oral contrast agent with a neutral taste and durable polymer bottle—made for patient ease and CT suite workflow[1,9]

Omnipaque is provided in an oral, ready to drink solution in two SKUs.

Omnipaque 9mg I/mL
Omnipaque 500 mL Oral Solution

- SKU: RTD-09
- NDC: 0407-1415-09
- Size and quantity: 10x500 mL Oral solution

Omnipaque 12mg I/mL
Omnipaque 500 mL Oral Solution

- SKU: RTD-12
- NDC: 0407-1416-12
- Size and quantity: 10x500 mL Oral solution

Omnipaque is provided in a dilutable solution in four SKUs.

- Omnipaque 180 mg I/mL
- Omnipaque 240 mg I/mL
- Omnipaque 300 mg I/mL
- Omnipaque 350 mg I/mL

References:

1. Stordahl A, Laerum F, Gjølberg T, Enge I. Water-soluble contrast media in radiology of small bowel obstruction: comparision of ionic and non-ionic contrast media. *Acta Radiol*. 1988;29:53-56.
2. Lönnemark M, Magnusson A. Oral contrast media in CT of the abdomen: iohexol of different concentrations as a gastrointestinal contrast medium. *Acta Radiol*. 1995;36:396-398.
3. McNamara MM, Lockhart ME, Fineberg NS, Berland LL. Oral contrast media for body CT: comparison of diatrizoate sodium and iohexol for patient acceptance and bowel opacification. *J Roentgenol*. 2010;195:1137-1141.
4. Parakh, Anushri, et al. Low-keV and Low-kVp CT for Positive Oral Contrast Media in Patients with Cancer: A Randomized Clinical Trial. *Radiology*. 2019;00:1-10.
5. Omnipaque [prescribing information]. Marlborough, MA: GE Healthcare: 2024.
6. Yeh B et al. Positive vs neutral OCM by Chansik An (PI: Ben Yeh). *AJR*. 2022.
7. Data on file. GE Healthcare Planned Investment; 2022.
8. https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-invests-138-million-in-cork-ireland-manufacturing-facility-to-address-increasing-contrast-media-demand
9. Smevik B, Westvik J. Iohexol for contrast enhancement of bowel in pediatric abdominal CT. Acta Radiol. 1990;31:601-604.

Customer Service 800 292 8514

Medical Affairs 800 654 0118 (option 2, then option 3)
or medical.affairs@gehealthcare.com

Reimbursement Hotline 800 767 6664

gehealthcare.com

OMNIPAQUE™
(IOHEXOL) INJECTION

October 2025 JB09360US