

# The known profile of diluted Omnipaque Injection in a ready-to-drink formulation

Omnipaque™ (iohexol) for Oral Use

**OMNIPAQUE™**  
(IOHEXOL) INJECTION

See approved indications on following page

## 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.

## MOST COMMON ADVERSE REACTIONS

- **Intrathecal Administration:** In clinical trials  $\geq 1\%$  of 1,531 adult patients included: headaches, pain (including backache, neckache, stiffness, and neuralgia), nausea, vomiting and dizziness. In clinical trials  $\geq 1\%$  of 152 pediatric patients included headache, vomiting and backache.
- **Intra-arterial or Intravenous Administration:** In clinical trials  $\geq 1\%$  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  $\geq 1\%$  of 391 pediatric patients included vomiting and nausea.
- **Oral or Rectal Administration for Examination of the Gastrointestinal Tract:** In clinical trials  $\geq 1\%$  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  $\geq 1\%$  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.



## 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.





#### 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.

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**OMNIPAQUE**<sup>™</sup>  
(IOHEXOL) INJECTION



Click an icon to learn more



Indications



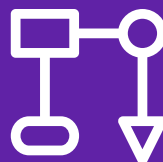
Patient  
considerations



Patient setting



Patient  
experience



Workflow  
efficiency



Case studies/  
clinical studies

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



Indications

**OMNIPAQUE™**  
(IOHEXOL) INJECTION





# Indications

## Omnipaque Injection for Oral Use

An FDA-approved oral contrast agent with a neutral taste and durable polymer bottle—made for patient ease and CT suite workflow<sup>4,6</sup>



Please see selected Important Safety Information throughout this sales aid and in the Full Prescribing Information, including Boxed Warning, [here](#) for additional important safety information.

**OMNIPaque™**  
(IOHEXOL) INJECTION



## Indications and Use – Adult

| Oral Administration                                                |                                                        | Concentration (mgI/mL) |
|--------------------------------------------------------------------|--------------------------------------------------------|------------------------|
| Radiographic examination of the GI tract                           |                                                        | undiluted 350 mg I/mL  |
| Oral Administration in Conjunction with Intravenous Administration |                                                        |                        |
| CT of the abdomen and pelvis                                       | dilute 240, 300, or 350 mg I/mL oral + 300 mg I/mL IV* |                        |
|                                                                    | or OOS 9 mg I/mL, 12 mg I/mL + 300 mg I/mL IV          |                        |

## Indications and Use – Pediatric

| Oral or Rectal Administration                                      |                                                               | Concentration (mgI/mL)          |
|--------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------|
| Radiographic examination of the GI tract                           |                                                               | undiluted 180, 240, 300 mg I/mL |
| Oral Administration in Conjunction with Intravenous Administration |                                                               |                                 |
| CT of the abdomen and pelvis                                       | dilute 240, 300, or 350 mg I/mL oral + 240 or 300 mg I/mL IV* |                                 |
|                                                                    | or OOS 9 mg I/mL, 12 mg I/mL + 240 or 300 mg I/mL IV          |                                 |

CT, computed tomography; GI, gastrointestinal; IA, intra-arterial; IV, intravenous; OOS, Omnipaque Oral Solution.

\*Refer to the full Prescribing Information for tables regarding preparation of diluted oral doses.

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



# Dilution guide

Omnipaque for oral administration may be diluted as follows:<sup>1</sup>

| To achieve                                                         | Add                                        |             | To                                                              |
|--------------------------------------------------------------------|--------------------------------------------|-------------|-----------------------------------------------------------------|
| One liter of contrast medium at a final concentration (mg I/mL) of | Stock concentration of Omnipaque (mg I/mL) | Volume (mL) | Water, milk, juice, carbonated beverage, or infant formula (mL) |
| 6                                                                  | 240                                        | 25          | 975                                                             |
|                                                                    | 300                                        | 20          | 980                                                             |
|                                                                    | 350                                        | 17          | 983                                                             |
| 9                                                                  | 240                                        | 38          | 962                                                             |
|                                                                    | 300                                        | 30          | 970                                                             |
|                                                                    | 350                                        | 26          | 974                                                             |
| 12                                                                 | 240                                        | 50          | 950                                                             |
|                                                                    | 300                                        | 40          | 960                                                             |
|                                                                    | 350                                        | 35          | 965                                                             |
| 15                                                                 | 240                                        | 63          | 937                                                             |
|                                                                    | 300                                        | 50          | 950                                                             |
|                                                                    | 350                                        | 43          | 957                                                             |
| 18                                                                 | 240                                        | 75          | 925                                                             |
|                                                                    | 300                                        | 60          | 940                                                             |
|                                                                    | 350                                        | 52          | 948                                                             |
| 21                                                                 | 240                                        | 88          | 912                                                             |
|                                                                    | 300                                        | 70          | 930                                                             |
|                                                                    | 350                                        | 60          | 940                                                             |

Dilutions of Omnipaque should be prepared just prior to use and any unused portion discarded after the procedure. Oral administration of diluted Omnipaque injection in conjunction with intravenous administration of Omnipaque injection for CT of the abdomen and pelvis in adults. See the full Prescribing Information for complete oral dosing and administration guidance.

Please see selected Important Safety Information throughout this sales aid and in the Full Prescribing Information, including Boxed Warning, [here](#) for additional important safety information.

**OMNIPaque™**  
(IOHEXOL) INJECTION



# Dosing

Omnipaque provides flexible usage options and is FDA-approved for oral administration as follows.<sup>1</sup>

## Adults



## Pediatrics



*Time to drink  
(up to 45 minutes)*



*Time to wait before imaging  
(adults: 0-40 minutes, pediatrics: 0-60 minutes)*

- The oral dosage may be given all at once or over a period of up to 45 minutes if there is difficulty in consuming the required volume<sup>1</sup> (see Table 13 of full Prescribing Information)
- Omnipaque IV to be administered up to 40 (adults)/60 (pediatric) minutes after consumption of the oral dose<sup>1</sup> (see Table 16 of full Prescribing Information)

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**OMNIPAQUE**<sup>™</sup>  
(IOHEXOL) INJECTION



Patient  
considerations

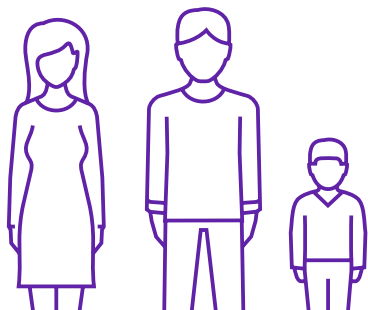
# OMNIPAQUE<sup>TM</sup>

(IOHEXOL) INJECTION





## Patient considerations



### Adults and pediatrics—Two options for your contrast needs<sup>1</sup>

**Omnipaque Oral Solution 9 mg I/mL and 12 mg I/mL or diluted selected strengths of Omnipaque Injection in conjunction with IV administration for CT of the abdomen and pelvis**

- **Adults:** In conjunction with Omnipaque 300 mg I/mL IV
- **Pediatrics:** In conjunction with Omnipaque 240 mg I/mL or 300 mg I/mL IV

CT, computed tomography; IV, Intravenous.

\*Less than 1% of orally administered iohexol is recovered in the urine, suggesting minimal amounts are absorbed from the normal gastrointestinal tract. This amount may increase in the presence of bowel perforation or bowel obstruction.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

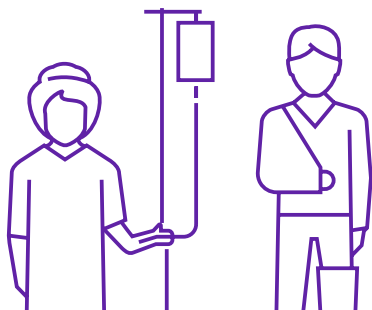
- **Cardiovascular Adverse Reactions:** Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main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

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



## Patient considerations *(cont'd)*



### Examples of patient considerations<sup>1</sup>

- Suspected bowel perforation or bowel obstruction
- Aspiration risk
- Patients with cancer
  - Current oncology and American College of Radiology guidelines advocate the use of positive oral contrast medium, despite its influence on workflow<sup>2</sup>
  - In a publication by Parakh et al in *Radiology*, it was seen that patients with cancer who undergo multiple CT exams have chemosensory alterations. This alteration may impact oral contrast intake. An oral contrast agent that is more palatable may help improve compliance of consuming the solution<sup>2</sup>

CT, computed tomography.

### 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.

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



Patient setting

# OMNIPAQUE<sup>TM</sup>

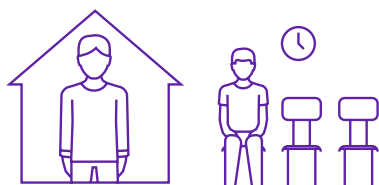
(IOHEXOL) INJECTION





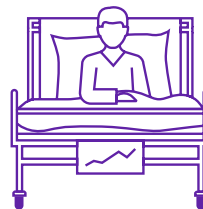
## Patient setting

### Omnipaque Oral Solution in conjunction with Omnipaque IV for CT of the abdomen and pelvis: Streamlines workflow in various settings



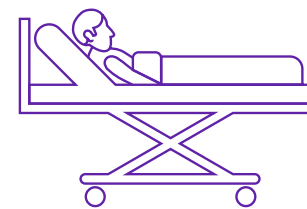
#### Outpatient setting

Easily identifiable bottle to allow 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 mixing procedures



#### Emergency department

Reduction in wait time of ordering positive contrast.  
Cup-to-table time potentially reduced

- Ready-to-drink formulation
- Provides consistent and accurate dosing

CT, computed tomography; IV, Intravenous.

*“Our emergency physicians do not see that oral contrast administration for CT hampers operational efficiency: in fact, they have expressed gratitude to our department for care in diagnosis...They are all acutely aware of the serious consequences of missed or incorrect diagnoses (either leading to inappropriate hospital admission or discharge), and will always choose good medical care over time-slashing, corner-cutting methods that impress the dashboard monitors, perhaps at the expense of excellence in patient care.”<sup>3</sup>*

#### IMPORTANT SAFETY INFORMATION

##### WARNINGS AND PRECAUTIONS

- **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.

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



Patient  
experience

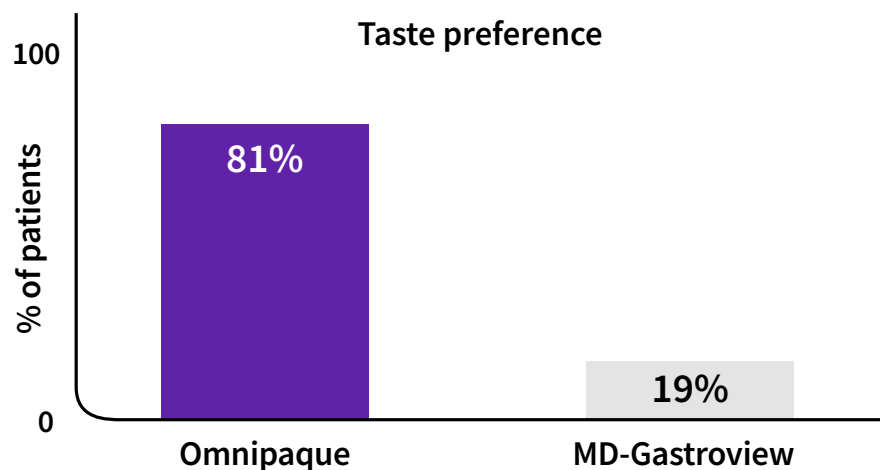
**OMNIPAQUE™**  
(IOHEXOL) INJECTION



## Patient experience

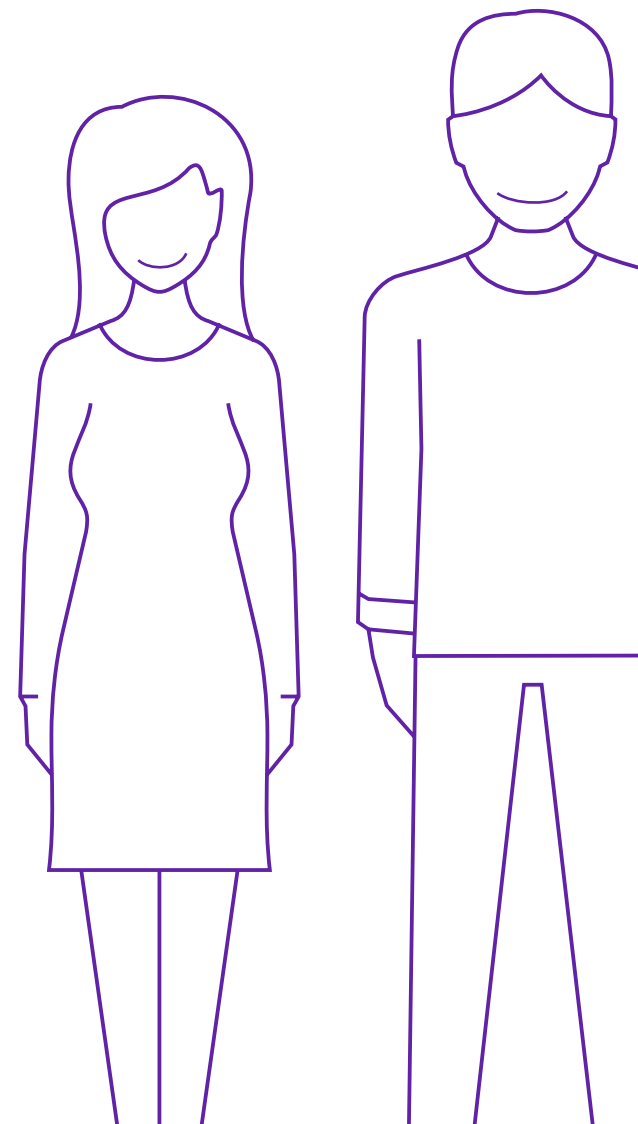
### A neutral taste for your patients<sup>4</sup>

- Patients in an abdominal computed tomography study drank the entire prescribed amount and said they would do so again, if necessary<sup>8</sup>
- Shown to have a neutral taste when compared with ionic Gastrografin<sup>®</sup> (diatrizoate meglumine and diatrizoate sodium solution USP)<sup>4</sup>
- Omnipaque received a significantly better taste preference score than did MD-Gastroview<sup>®</sup> (diatrizoate meglumine and diatrizoate sodium solution USP) ( $P<0.001$ )<sup>5</sup>



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

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**OMNIPAQUE**<sup>™</sup>  
(IOHEXOL) INJECTION



## Patient experience *(cont'd)*

### A neutral taste to help kids drink<sup>6</sup>

- A nonionic, low-osmolar contrast medium indicated for oral use in both adults and children<sup>1</sup>
- Shown to have a neutral taste when compared with ionic diatrizoate<sup>6</sup>
- In a study of 160 pediatric patients by Smevik and Westvik, when diluted with a beverage of the child's choice, 98% of children drank the entire dose<sup>6</sup>
- Provides good visualization of the intestines and is proven suitable for gastrointestinal (GI) use in infants and children<sup>7</sup>



#### INDICATIONS:

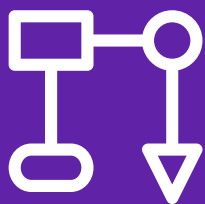
**OMNIPAQUE is indicated for oral or rectal procedures for:** • Radiographic examination of the gastrointestinal tract in adults and pediatric patients  
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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



Workflow  
efficiency

**OMNIPAQUE™**  
(IOHEXOL) INJECTION



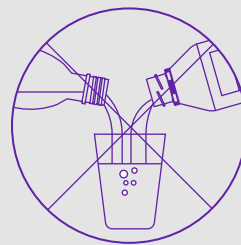


## Workflow efficiency

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<sup>1</sup>**

### Minimize process to mix oral contrast:

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

*“...This ready-to-drink formulation may help eliminate the errors involved with diluting contrast agents for oral use. It will help us to optimize operational efficiency while ensuring that we continue to provide our patients with a well-characterized contrast agent.”*

**Elliot K. Fishman, MD**, Professor of Radiology and Radiological Sciences and Director of Diagnostic Imaging and Body CT at Johns Hopkins Medicine

Dr. Fishman is a consultant of GE HealthCare.

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



Case studies/  
clinical studies

# OMNIPAQUE™ (IOHEXOL) INJECTION

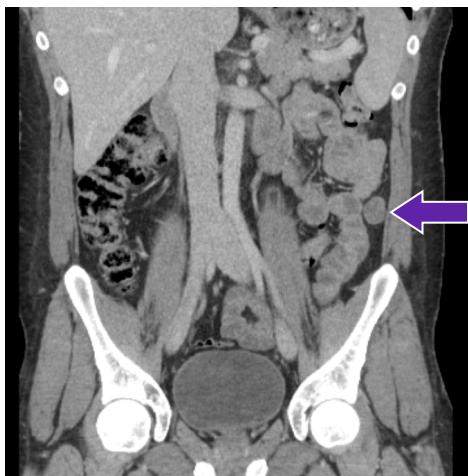




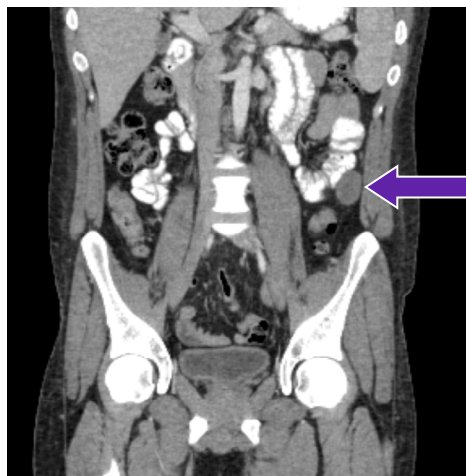
## Diluted Omnipaque™ (iohexol) Injection administered orally in conjunction with IV Omnipaque

### Case study: 26, male, metastasized testicular carcinoma

Case study courtesy of Dr. Benjamin Yeh, University of California, San Francisco, CA



Oral water, 1,000 mL  
Tumor missed



Oral iohexol 7 mg I/mL, 1,000 mL  
Two months later, tumor seen

#### 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

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#### IMPORTANT SAFETY INFORMATION

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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



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**OMNIPAQUE™**  
(IOHEXOL) INJECTION



## Study designs for referenced clinical studies

**Stordahl A, Laerum F, Gjølborg T, Enge I. Water-soluble contrast media in radiography of small bowel obstruction: comparison of ionic and non-ionic contrast media. *Acta Radiol.* 1988;29:53-56.**

A randomized, double-blind, prospective, single-center study of diagnostic quality, adverse effects, and taste in consecutive pass-through examinations for gastrointestinal obstruction in adults, using 100 mL of oral (undiluted) iohexol 350 mg I/mL (N=25) or sodium diatrizoate 370 mg I/mL (N=25). Patient groups were similar except for the overrepresentation of women in the 50-to-60 and 60-to-70 age groups in the iohexol and sodium diatrizoate groups, respectively. Taste results were not reported for one patient taking iohexol and two patients who took sodium diatrizoate.

**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. *AJR.* 2010;195:1137-1141.**

The McNamara study was a randomized, double-blind, prospective, single-center trial of taste rating (5-point Likert scale), diagnostic opacification score, and adverse events of abdominal–pelvic contrast enhanced CT of adults using 900 mL each of diluted oral solutions of iohexol (N=149; 9.0 mg I/mL iodine) or diatrizoate sodium (151 enrolled; 148 available for analysis; 9.17 mg I/mL iodine) in addition to intravenous iopamidol 370 mg I/mL. A separate direct, double-blind taste preference comparison was conducted in which patients compared 30 mL of each diluted agent using a 3-point scale (preferred A, or B, or no preference). Patient age groups were similar.

**Smevik B, Stake G. Omnipaque as contrast medium for bowel opacification in abdominal CT in infants and children. In: Kaufman HJ, ed. *Contrast Media in Child Radiology.* Basel, Switzerland: Karger; 1986:79-80.**

A nonrandomized, observational, single-center study of radiographic quality and taste acceptance in 32 consecutive gastrointestinal examinations of infants and children (13 males and 19 females, aged 31 weeks to 13 years). Contrast was administered as iohexol 350 mg I/mL diluted to 7 mg I/mL and administered orally (120 to 500 mL), via gastric tube (60 to 300 mL), or rectally (60 to 120 mL) in pediatric patients (0 to 14 years of age). In 25 patients 3 mL/kg body weight of iohexol 350 mg I/mL was also administered intravenously. Taste was assessed in 20 patients and diagnostic quality, bowel enhancement, and safety in all 32. The undiluted strength and IV doses were greater than those specified in approved US labeling.

(Continued on following screen)



## Study designs for referenced clinical studies *(cont'd)*

**Smevik B, Westvik J. Iohexol for contrast enhancement of bowel in pediatric abdominal CT. *Acta Radiol.* 1990;31:601-604.**

A nonrandomized, prospective, single-center study of contrast enhancement, taste, and microbiological quality in abdominal CT, with iohexol (7 mg I/mL, N=32 or 6 mg I/mL, N=128) diluted with water, juice, lemonade, or milk. Iohexol was administered orally (N=142), via feeding tube (N=5), or rectally (N=19) in pediatric patients (0 to 16 years of age); six patients received the drug both orally and rectally. Taste acceptance was recorded only for the 7-mgI/mL strength. Both strengths were less than the range specified in approved labeling and the 6-mgI/mL doses were prepared from vials of contrast left over from angiocardiology studies (stored from five days to two months). Oral dose volumes (0-1500 mL) were outside the range of approved US labeling. The concurrent dose of IV contrast was not specified.

**Lönnemark M, Magnusson A. Oral contrast media in CT of the abdomen. *Acta Radiol.* 1995;36:396-398.**

A double-blind, randomized, prospective, single-center study of diagnostic quality, taste, and adverse experiences for 800 mL of three oral concentrations (4.5, 6.75, and 9 mg I/mL) of iohexol prepared from a 350-mg I/mL formulation. Subjects were adult patients referred for abdominal CT. The taste and consistency of the contrast media were recorded on a visual analogue scale of 0% (poor acceptance) to 100% (good acceptance). The contrast media were ingested in four 200-mL portions, one every 40 minutes, during two hours prior to the CT examination. Patient demographics were similar between dose groups. The 4.5-mg I/mL dose is below the minimum in approved US labeling. The labeled concurrent intravenous dose of iohexol used was not identified.

**Stake G, Smevik B. Iohexol as contrast medium for the gastrointestinal tract in childhood. In: Kaufman HJ, ed. *Contrast Media in Child Radiology*. Basel, Switzerland: Karger; 1986:107-109.**

A nonrandomized, observational, single-center study of radiographic quality and taste acceptance in gastrointestinal examinations, using iohexol at full strength (350 mg I/mL, N=4) or diluted with water (175 mg I/mL, N=29). Iohexol was administered orally (N=14; taste acceptance reported for 11), via feeding tube (N=17), or rectally (N=2) in pediatric patients (0 to 14 years of age). The strengths and doses were outside of those specified in approved US labeling. The concurrent dose of intravenous contrast was not specified.



## 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-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.

*(Continued on following screen)*



## OMNIPAQUE (IOHEXOL) INJECTION, HCP IMPORTANT SAFETY INFORMATION *(continued)*

- **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  $\geq 1\%$  of 1,531 adult patients included: headaches, pain (including backache, neckache, stiffness, and neuralgia), nausea, vomiting and dizziness. In clinical trials  $\geq 1\%$  of 152 pediatric patients included headache, vomiting and backache.
- **Intra-arterial or Intravenous Administration:** In clinical trials  $\geq 1\%$  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  $\geq 1\%$  of 391 pediatric patients included vomiting and nausea.
- **Oral or Rectal Administration for Examination of the Gastrointestinal Tract:** In clinical trials  $\geq 1\%$  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  $\geq 1\%$  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](http://www.fda.gov/medwatch).

## References

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**Customer service** 800 292 8514

**Medical affairs** 800 654 0118 (option 2, then option 3)  
or [medical.affairs@gehealthcare.com](mailto:medical.affairs@gehealthcare.com)

**Reimbursement hotline** 800 767 6664  
[gehealthcare.com](http://gehealthcare.com)

**OMNIPAQUE™**  
(IOHEXOL) INJECTION

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