GE HealthCare

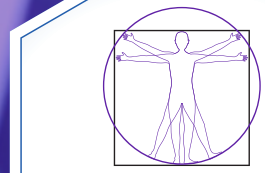
KEEPING RADIOLOGY MOVING

Efficacy around the body, efficiency around the world

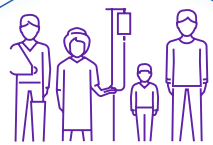
OMNIPAQUE™
(IOHEXOL) INJECTION
for
Oral Use

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

Click an icon to learn more



INDICATIONS

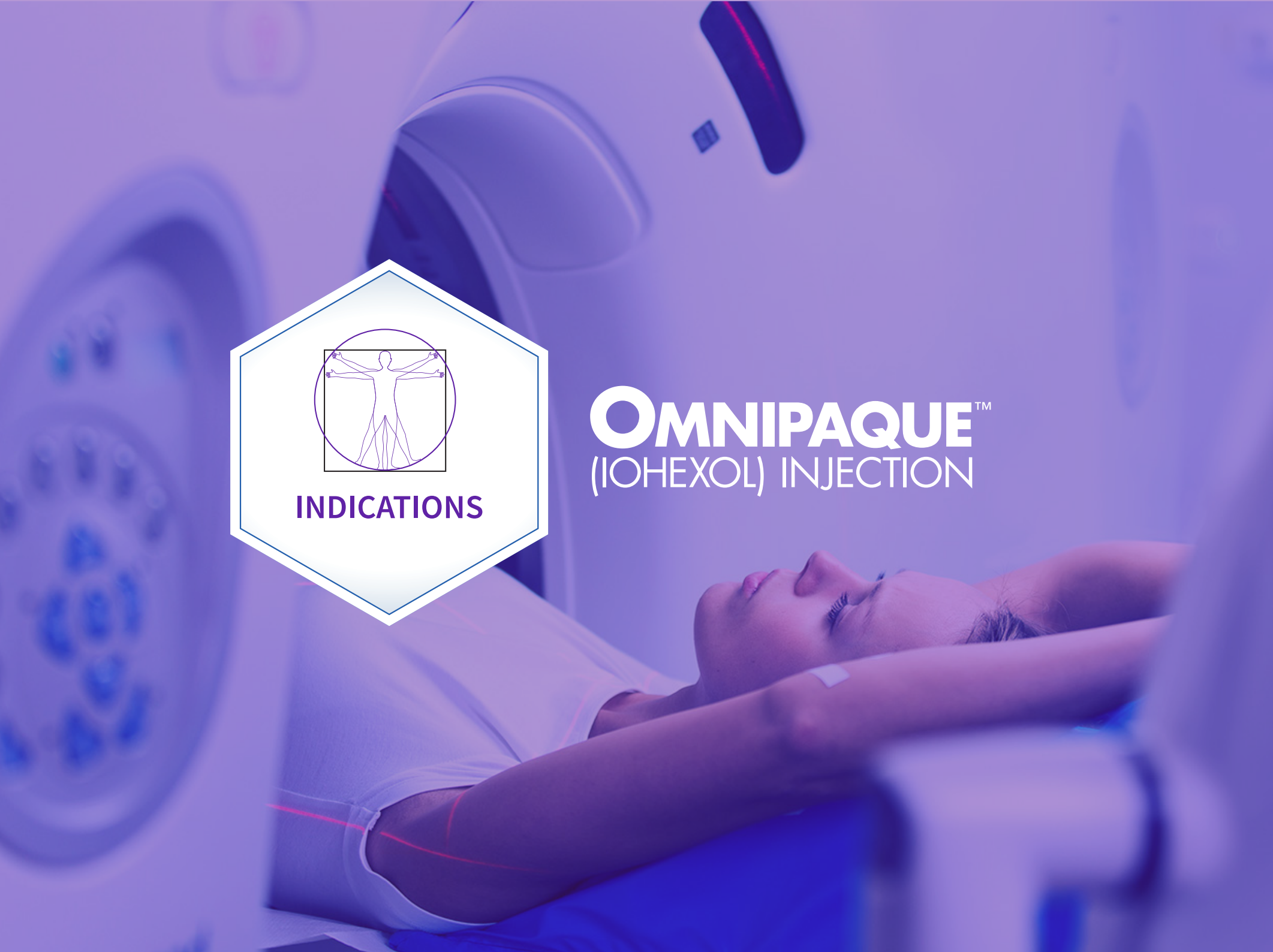


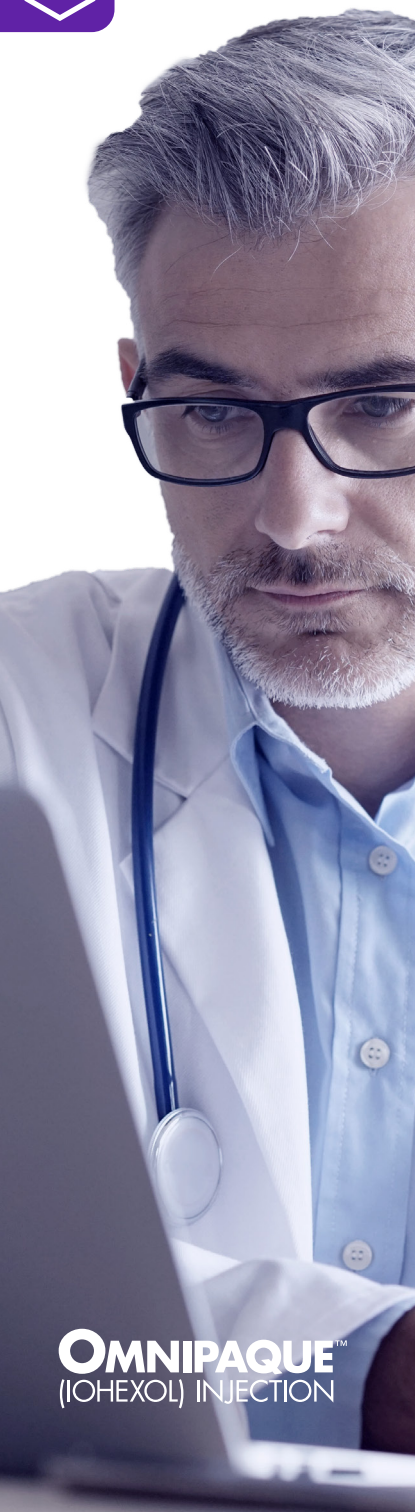
PATIENT CONSIDERATIONS

PATIENT EXPERIENCE

CASE STUDIES/ CLINICAL STUDIES

OMNIPAQUE™
(IOHEXOL) INJECTION


INDICATIONS
OMNIPAQUE™
(IOHEXOL) INJECTION



Indications

Omnipaque Injection for Oral Use

Iohexol is the first and only low-osmolar iodinated contrast medium approved for oral use in Canada

*Omnipaque 240 mgI/mL, 300 mgI/mL, 350 mgI/mL,

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

Indications and Use – Adult

Oral Administration	Concentration (mgI/mL)
Radiographic examination of the GI tract	undiluted 300, 350 mgI/mL
Oral Administration in Conjunction with Intravenous Administration	
CT of the abdomen	dilute 240, 300, or 350 mgI/mL oral + 300 mgI/mL IV*

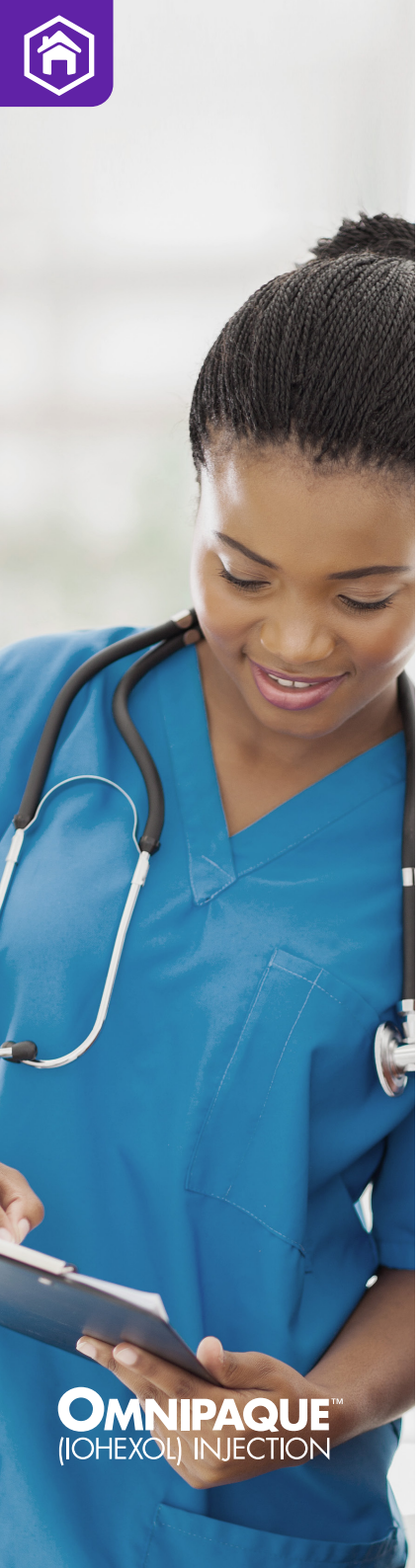
Indications and Use – Pediatric

Oral or Rectal Administration	Concentration (mgI/mL)
Radiographic examination of the GI tract	undiluted 240, 300 mgI/mL
Oral Administration in Conjunction with Intravenous Administration	
CT of the abdomen	dilute 240, 300, or 350 mgI/mL oral + 240 or 300 mgI/mL IV*

CT, computed tomography; **GI,** gastrointestinal; **IA,** intra-arterial; **IV,** intravenous;

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

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.



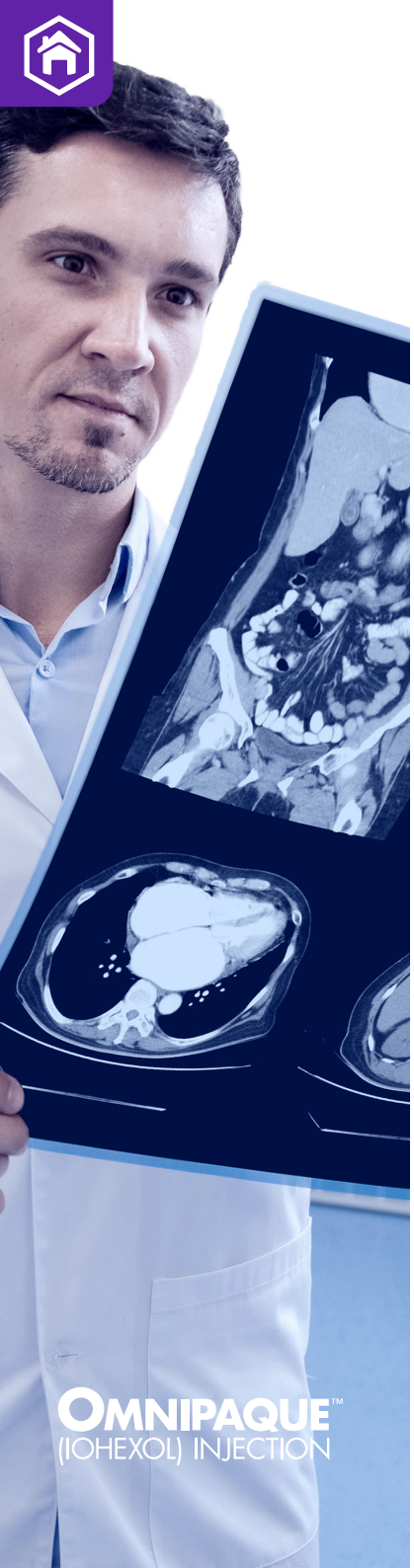
Dilution Guide

Omnipaque for oral administration may be diluted as follows.[1]

To Achieve	Add		To
One liter of contrast medium at a final concentration (mgI/mL) of	Stock concentration of Omnipaque (mgI/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
24	240	100	900
	300	80	920
	350	69	931
27	240	113	887
	300	90	910
	350	77	923
29	240	120	880
	300	97	903
	350	83	917

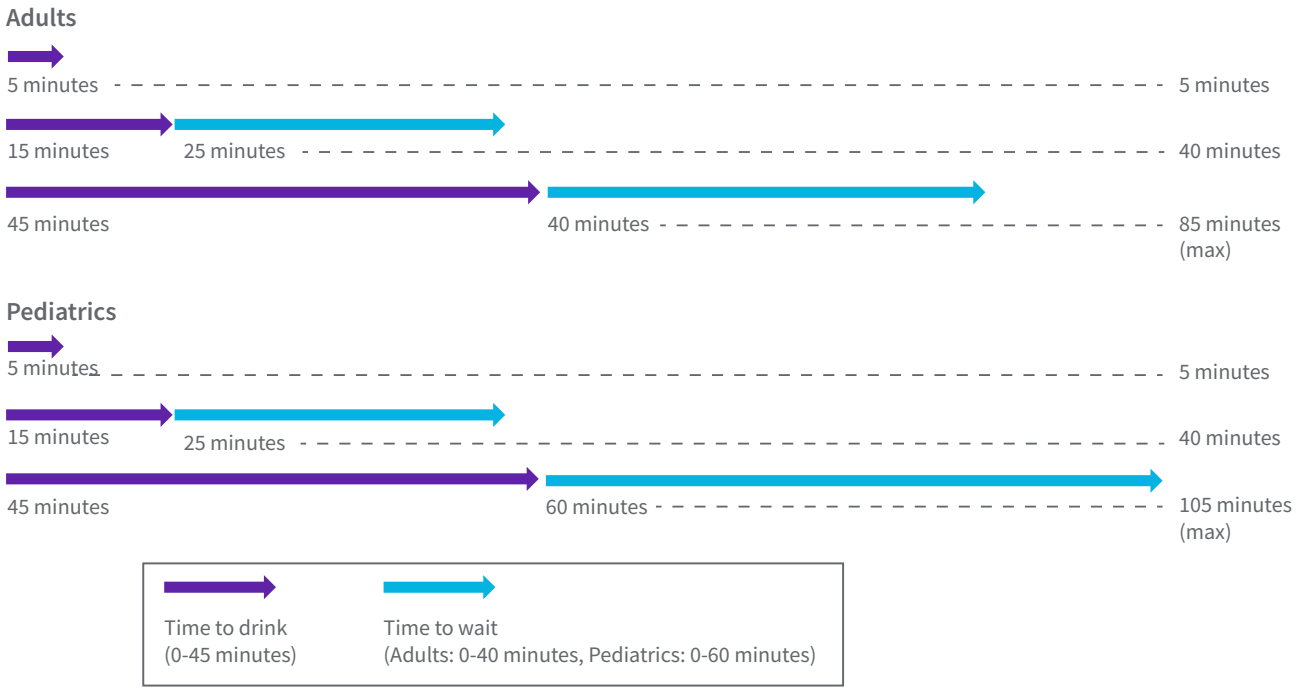
See the full Prescribing Information for complete oral dosing and administration guidance.

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.



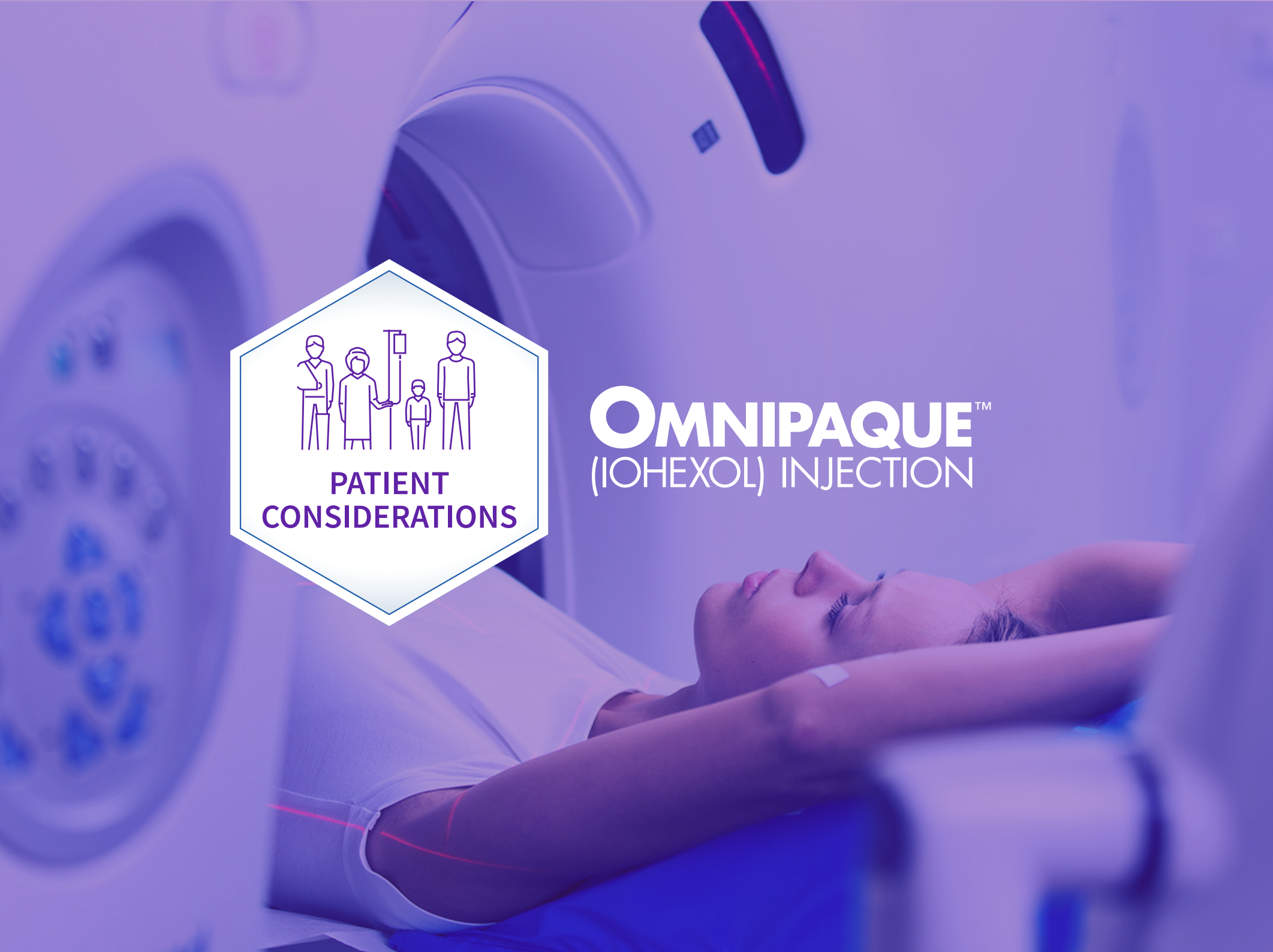
Dosing

Omnipaque is Health Canada-approved for oral administration as follows:[1]



- 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[1]
- Omnipaque IV to be administered up to 40 (adults)/60 (pediatric) minutes after consumption of the oral dose[1]

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.


PATIENT
CONSIDERATIONS
OMNIPAQUE™
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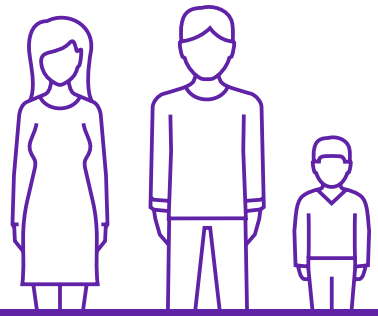
Patient considerations



Adults and pediatrics

Diluted selected strengths of Omnipaque Injection in conjunction with IV administration for CT of the abdomen

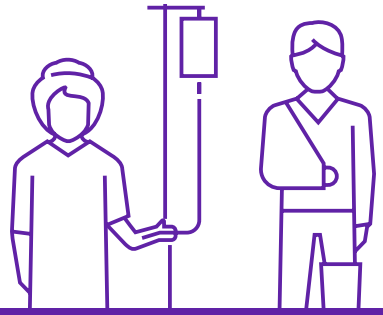
- **Adults:** In conjunction with Omnipaque 300 mgI/mL IV
- **Pediatrics:** In conjunction with Omnipaque 240 mgI/mL or 300 mgI/mL IV

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.[1]

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

Patient considerations (cont'd)

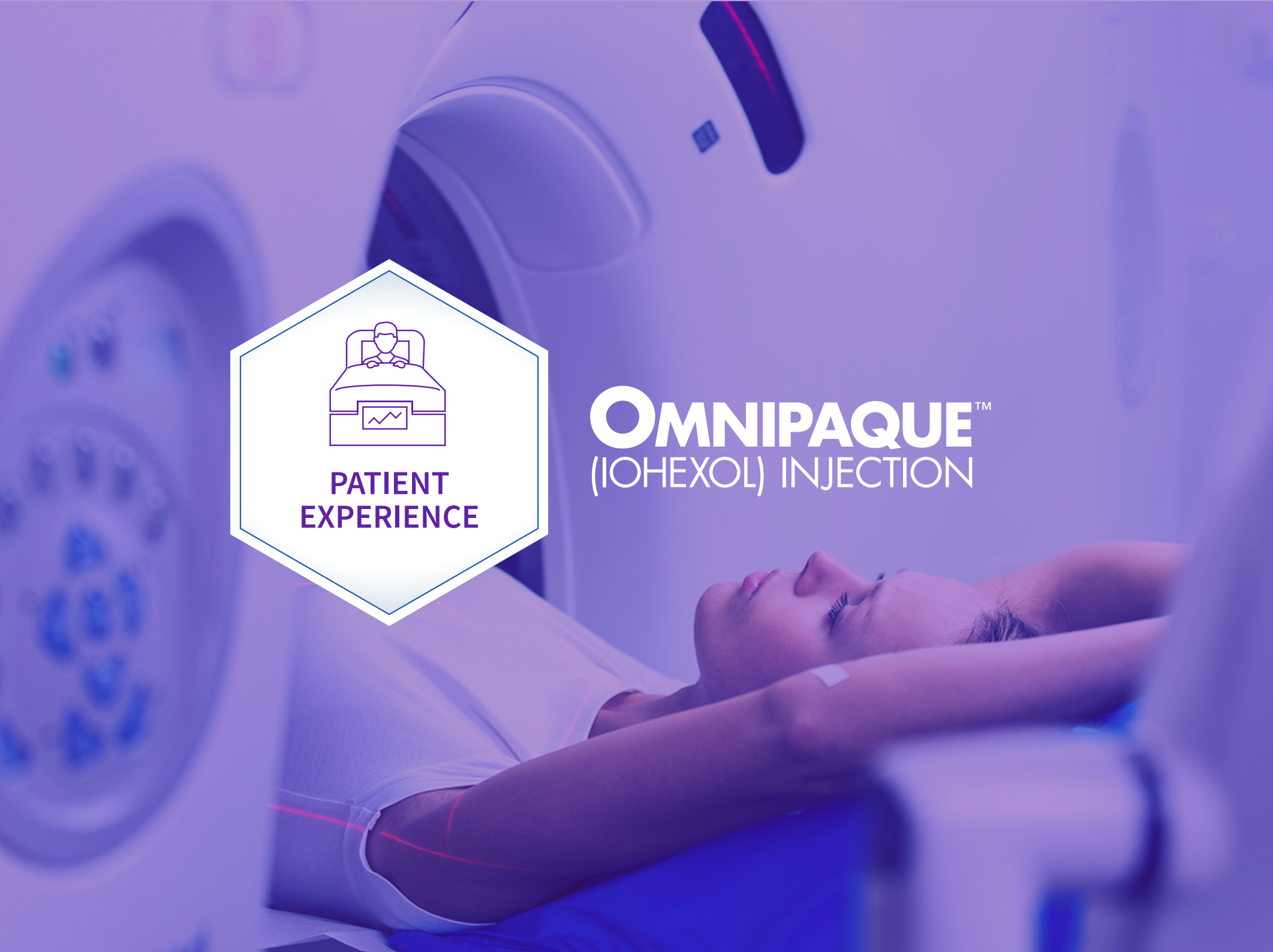


Examples of patient considerations[1]

- **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[2]
  - 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[2]

CT, computed tomography.

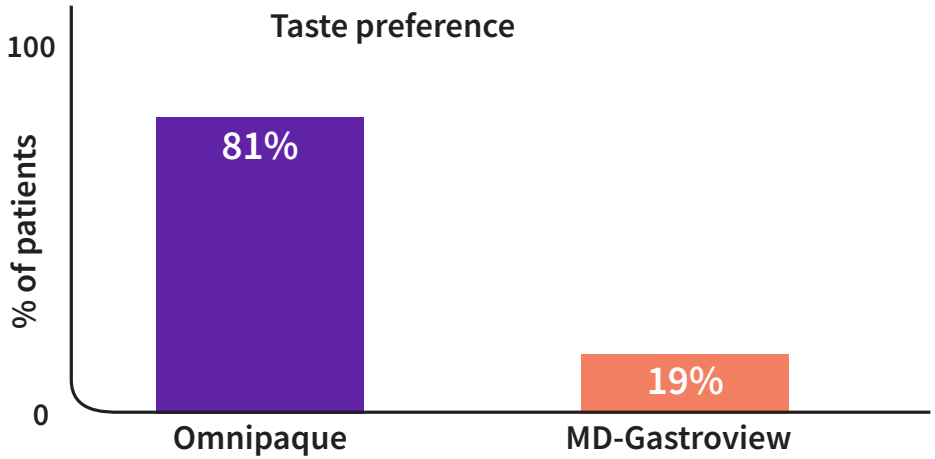
Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

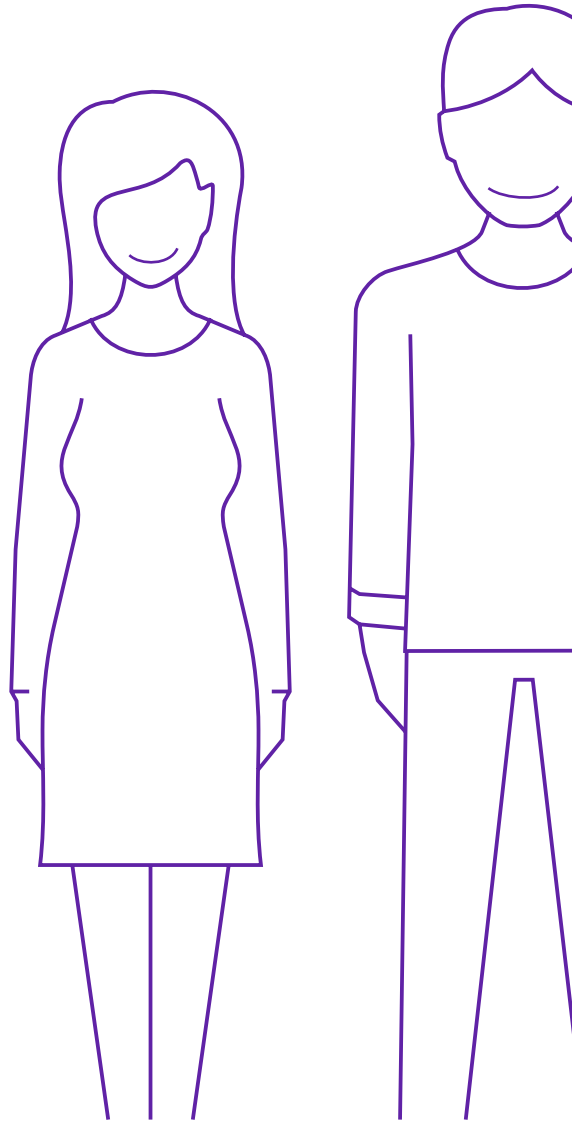

PATIENT
EXPERIENCE
OMNIPAQUE™
(IOHEXOL) INJECTION

Patient experience

A neutral taste for your patients[4]

- Patients in an abdominal computed tomography study drank the entire prescribed amount and said they would do so again, if necessary[9]
- Shown to have a neutral taste when compared with ionic Gastrografin® (diatrizoate meglumine and diatrizoate sodium solution USP)[4]
- Omnipaque received a significantly better taste preference score than did MD-Gastroview® (diatrizoate meglumine and diatrizoate sodium solution USP) (*P*<0.001)[5]





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

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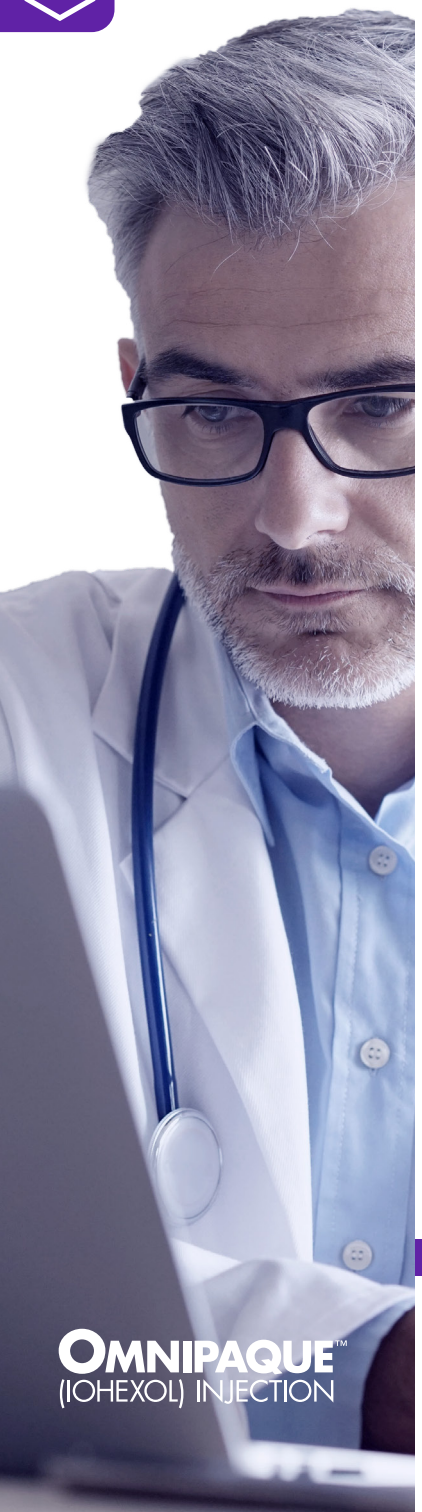
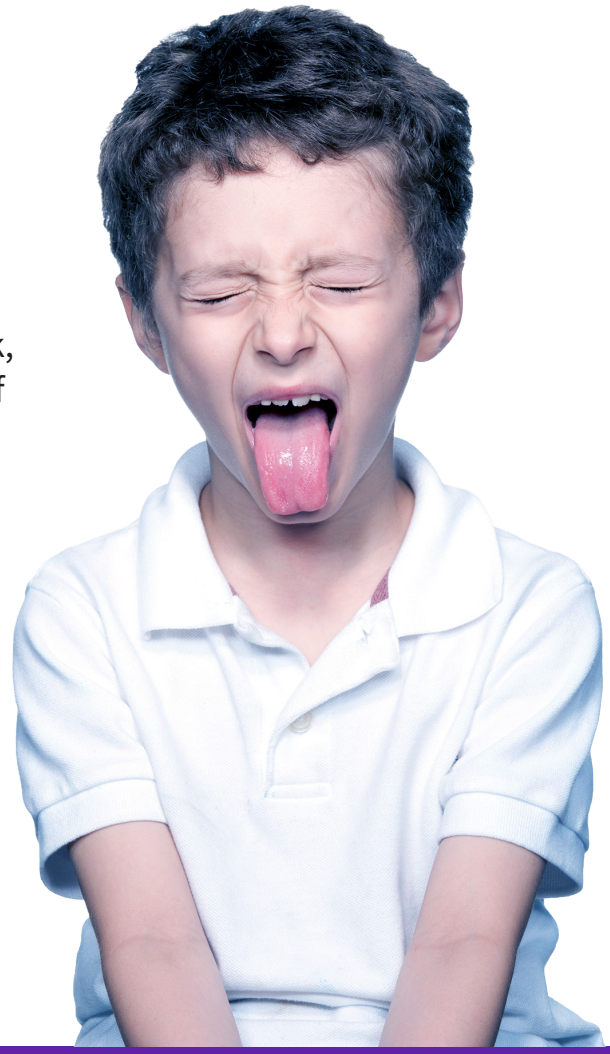


Patient experience

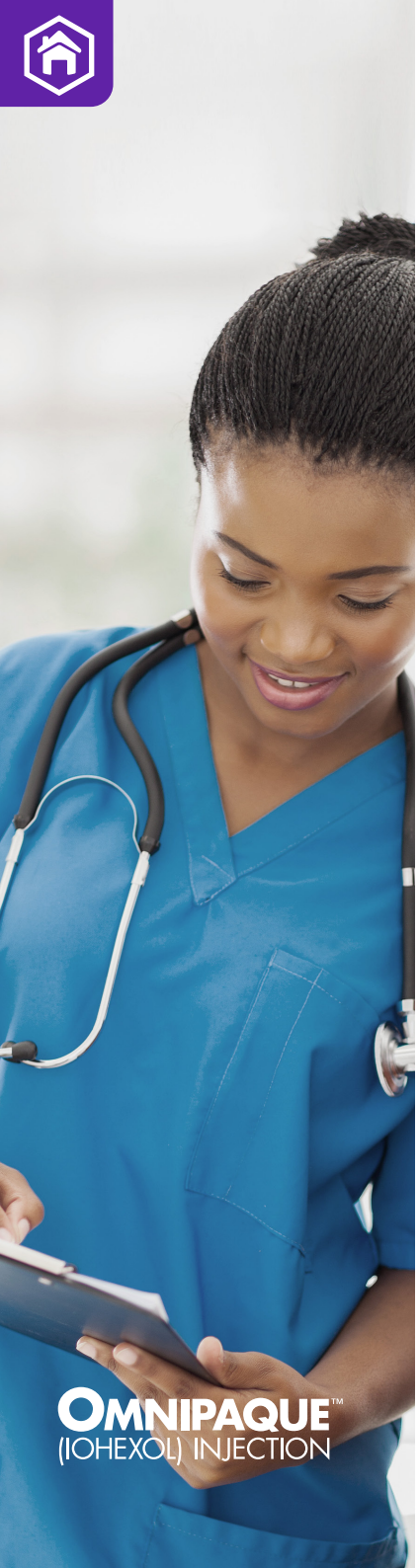
A neutral taste to help kids drink[6]

- A nonionic, low-osmolar contrast medium indicated for oral use in both adults and children[1]
- Shown to have a neutral taste when compared with ionic diatrizoate[6]
- 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[6]
- Provides good visualization of the intestines and is proven sutiable for gastrointestinal (GI) use in infants and children[7,8]



Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

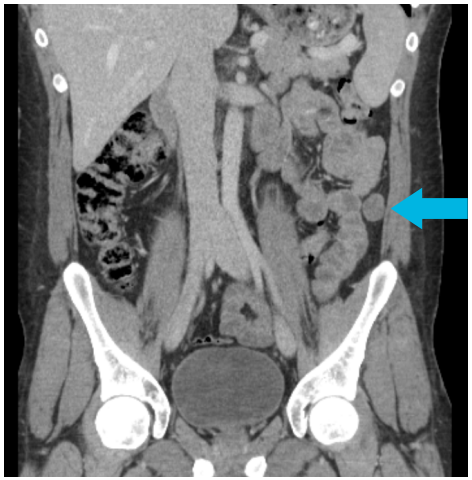

CASE STUDIES/
CLINICAL
STUDIES
OMNIPAQUE™
(IOHEXOL) INJECTION



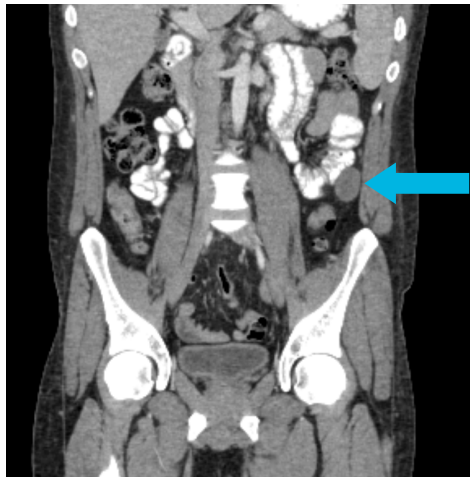
Diluted Omnipaque™ (iohexol) Injection adminstered orally in conjunction with IV Omnipaque

Case study: 26, male, metastasized testicular carcinoma

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

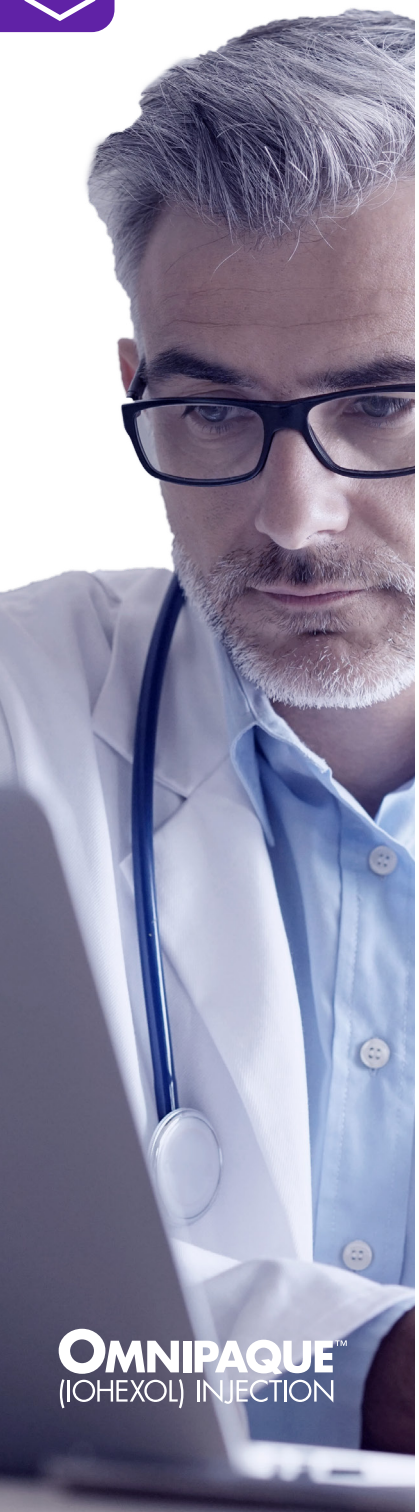


Oral water, 1,000 mL
Tumor missed



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

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.



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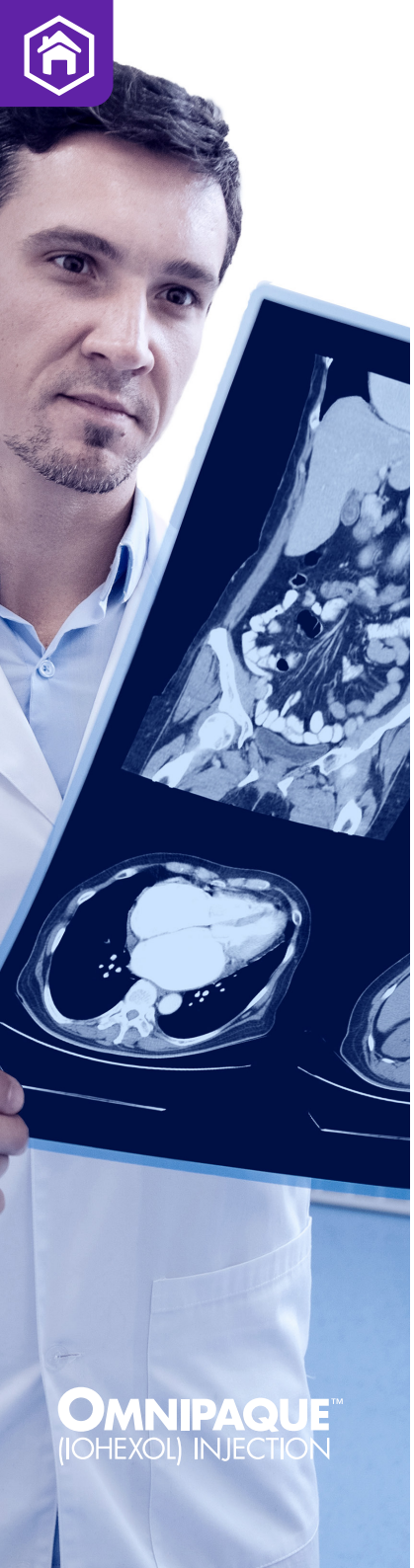
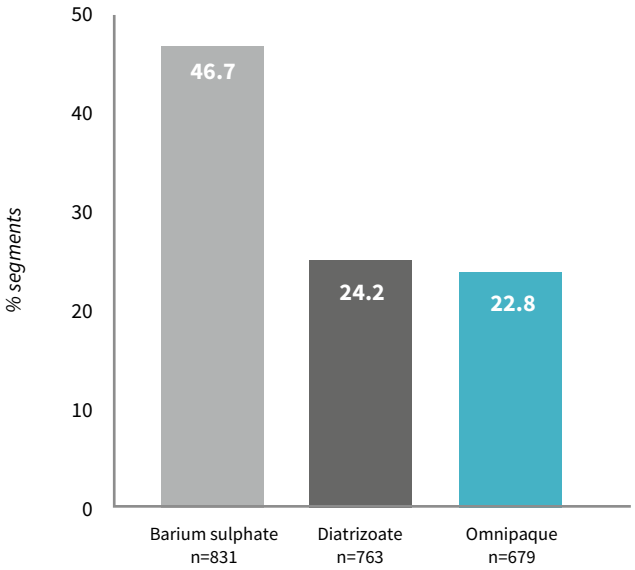


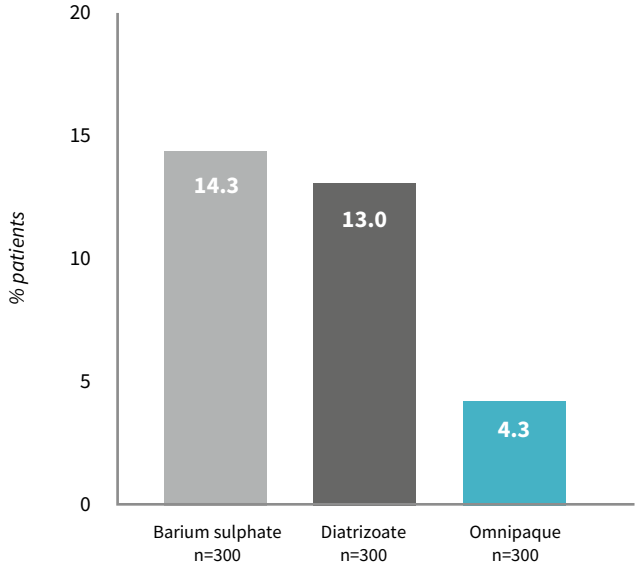
How does bowel lumen opacification with Omnipaque compare with other oral CM?

In a retrospective blinded analysis of CT scans, the frequency of non-uniform bowel opacification, as well as the presence of artifacts, was lower with Omnipaque than for diatrizoate or barium sulphate[10]

Frequency of bowel lumen heterogeneity[10]



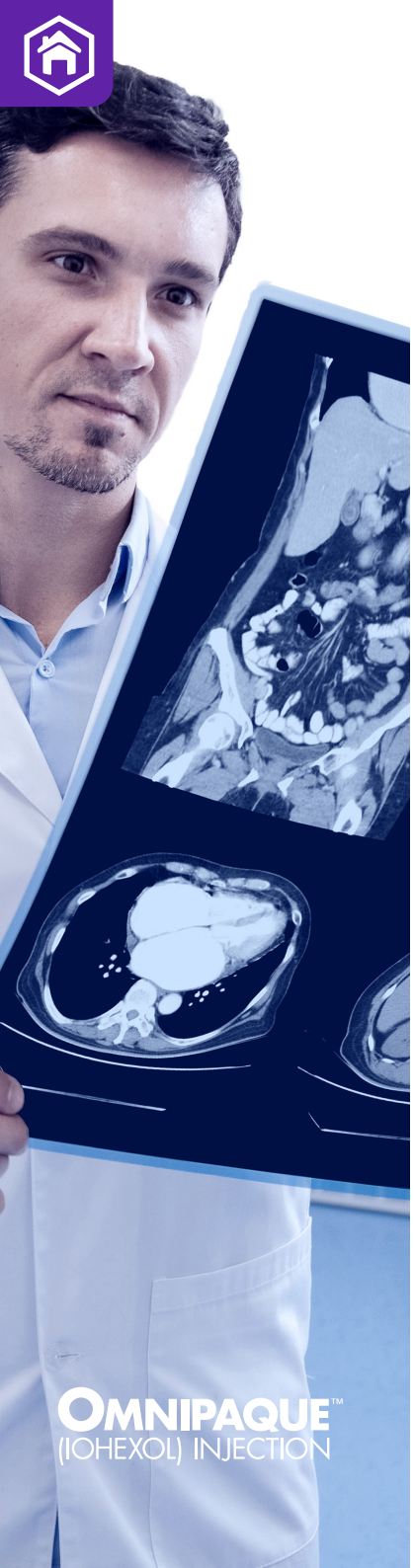
Presence of artifacts[10]



Adapted from Winklhofer 2019[10]

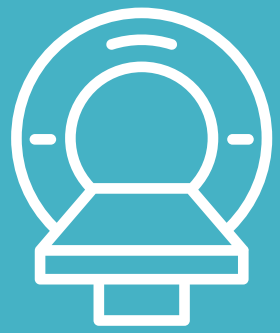
CM: contrast medium/media
SPC: summary of product characteristics

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

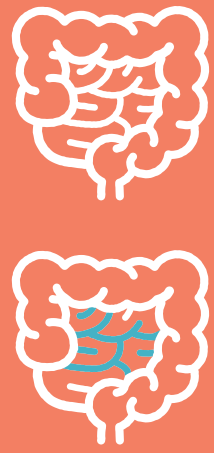


Evidence supports use of positive vs neutral oral contrast for malignant deposits on abdominal CT[11]

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:

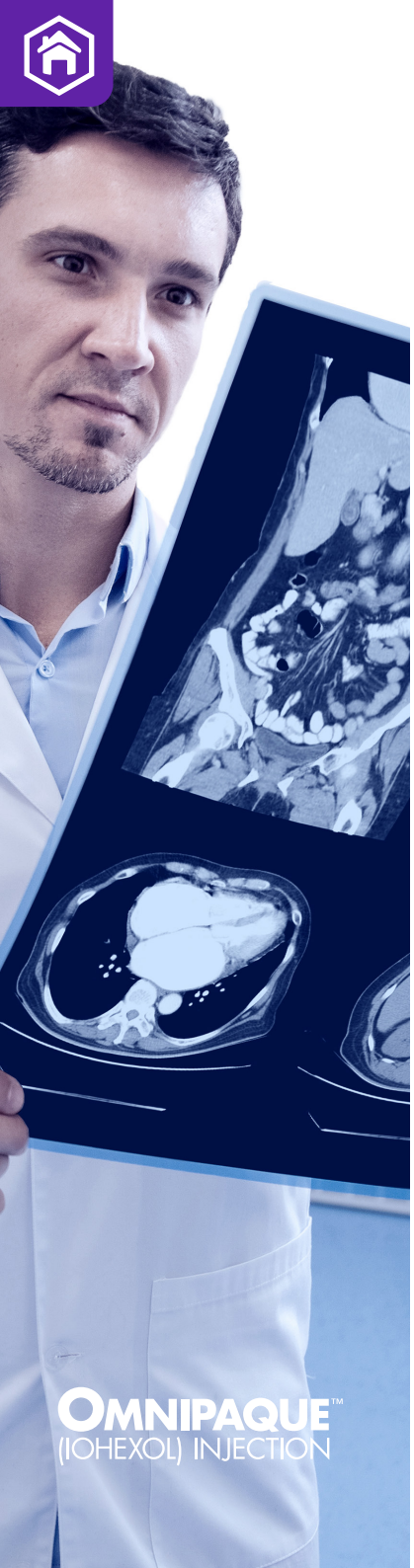
NPV: 65.8% for positive agent with adequate bowel filling

NPV: 45.2% for positive agent with inadequate bowel filling

NPV: 35.2% for neutral agent

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

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.



Study designs for referenced clinical studies

Stordahl A, Laerum F, Gjølberg 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 mgI/mL (N=25) or sodium diatrizoate 370 mgI/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 mgI/mL iodine) or diatrizoate sodium (151 enrolled; 148 available for analysis; 9.17 mgI/mL iodine) in addition to intravenous iopamidol 370 mgI/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.

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Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

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 mgI/mL, N=32 or 6 mgI/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 angiocardiography 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 mgI/mL) of iohexol prepared from a 350-mgI/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-mgI/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 mgI/mL, N=4) or diluted with water (175 mgI/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.

Please see approved indications and Important Safety Information for Omnipaque™ (iohexol) at the back.

Product Indications and Clinical Use – Omnipaque™ (iohexol injection USP)

Adults

Subarachnoid: Omnipaque 240 (iohexol 240 mg I/mL) and Omnipaque 300 (iohexol 300 mg I/mL) are indicated for subarachnoid administration in adults for lumbar, thoracic, cervical and total columnar myelography. Delayed CT scans of the spinal subarachnoid space and of the intracranial CSF spaces may be obtained at the appropriate time following myelography, taking advantage of delayed opacification by the physiological cephalad circulation of the opacified CSF. **Intravascular:** Omnipaque 350 (iohexol 350 mg I/mL) is indicated in adults for left ventriculography, coronary arteriography, intravenous contrast enhancement for computed tomographic head and body imaging, peripheral arteriography, excretory urography, and intravenous digital subtraction arteriography. Omnipaque 300 (iohexol 300 mg I/mL) is indicated in adults for cerebral arteriography, intravenous contrast enhancement for computed tomographic head and body imaging, peripheral arteriography, peripheral venography, and excretory urography. Omnipaque 240 (iohexol 240 mg I/mL) is indicated in adults for intravenous contrast enhancement in computed tomographic head imaging, and for peripheral venography. **Arthrography:** Omnipaque 300 (iohexol 300 mg I/mL) or Omnipaque 240 (iohexol 240 mg I/mL) is recommended in adults for arthrography of the knee joint. Omnipaque 300 (iohexol 300 mg I/mL) is recommended for arthrography of the shoulder joint in adults. **Oral:** Omnipaque 300 and Omnipaque 350 are indicated in adults for oral administration for radiographic imaging of the gastrointestinal tract (including esophagus, stomach, small bowel and colon). Omnipaque 240, Omnipaque 300 and Omnipaque 350 diluted to 6 to 9 mg I/mL are indicated for oral administration in adults for CT of the abdomen and pelvis in conjunction with intravenous administration of Omnipaque.

Pediatrics

Intravascular: Omnipaque 350 (iohexol 350 mg I/mL) is indicated in children for angiocardiography. Omnipaque 300 (iohexol 300 mg I/mL) is indicated in children for excretory urography and may be used in infants for angiocardiography. **Oral, Rectal, or by Enteric Tube:** Omnipaque 240 and Omnipaque 300 are indicated for oral, rectal, or by enteric tube administration for radiographic imaging of the gastrointestinal tract (including esophagus, stomach, small bowel and colon). Omnipaque 240, Omnipaque 300 and Omnipaque 350 diluted to 9 to 29 mg I/mL are indicated for oral administration in children for CT of the abdomen and pelvis in conjunction with intravenous administration of Omnipaque.

CONTRAINDICATIONS

- Omnipaque (iohexol) is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Omnipaque is contraindicated in patients with clinically significant impairment of both hepatic and renal function.

(Continued on following screen)

OMNIPAQUE™
(IOHEXOL) INJECTION

Important Safety Information (Cont'd)

SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- The possibility of hypersensitivity including serious, life-threatening, fatal anaphylactic/anaphylactoid reactions should always be considered. The majority of serious undesirable effects occur within the first 30 minutes. Late-onset (that is 1 hour or more after application) hypersensitivity reactions can occur. Patients should be observed for at least 30 minutes after administration of Omnipaque.
- Serious or fatal reactions have been associated with the administration of water-soluble contrast media. It is of utmost importance that a course of action be carefully planned in advance for immediate treatment of serious reactions, and that adequate facilities and appropriate personnel be readily available in case a severe reaction should occur.

- Concentration used: Use the recommended Omnipaque concentration for the particular procedure to be performed
- Caution is advised in patients with:
  - Sickle cell; fluid restriction is not advised in individuals who are homozygous for sickle cell disease
  - Multiple myeloma
  - Severe cardiovascular disease, hyperthyroidism, a history of bronchial asthma or other allergic manifestations, or sensitivity to iodine
  - Pheochromocytoma
  - Endotoxemia or elevated body temperature
- Elderly and pediatric patients may present a greater risk
- Thyroid dysfunction: Omnipaque, like all other iodinated contrast media, may induce changes in thyroid function in some patients. Transient hyperthyroidism or hypothyroidism has been reported following iodinated contrast media administration to adult and pediatric patients. Decreased levels of thyroxine (T4) and triiodothyronine (T3) and increased levels of TSH were reported after exposure to ICM in infants, especially preterm infants, which remained for up to a few weeks or more than a month. Hypothyroidism in infants may be harmful for growth and development, including mental development, and may require treatment
- Thyroid function should be checked in neonates following administration of iodinated contrast agents to mothers during pregnancy
- Contrast media-induced nephrotoxicity. Patients with pre-existing conditions that alter renal function are at increased risk
- Inaccurate thyroid function tests in the several weeks following radiopaque examination
- Potential for thyroid storm in patients with hyperthyroidism or autonomously functioning thyroid nodule
- Risk of severe adverse reactions in patients on adrenergic beta-blockers
- Risk of clinical deterioration, convulsions, and serious temporary or permanent neurological complications in patients with increased intracranial pressure, cerebral thrombosis or embolism, primary or metastatic cerebral lesions, subarachnoid hemorrhage, arterial spasm, transient ischemic attacks, and in any condition when the blood-brain barrier is breached or transit time of the contrast media through the cerebral vasculature is prolonged
- Caution in dose selection for patients with renal insufficiency
- Risk of acute renal failure in patients with pre-existing renal impairment, sepsis, hypotension, dehydration, advanced vascular disease, congestive heart disease, diabetes mellitus, multiple myeloma or other paraproteinacious diseases, the elderly with age-related renal impairment, and those on medications that alter renal function

(Continued on following screen)

Important Safety Information (Cont'd)

- Patients should be adequately hydrated
- Safety and efficacy not established in pregnant women or those who are breastfeeding

Subarachnoid Use: Myelography should not be performed in the presence of infection; caution should be taken with patients on anticonvulsants and at risk of seizures.

Vascular Use: Serious thromboembolic events; patients with serum creatinine above 3 mg/dL; extreme caution with vasopressors; general anesthesia; metformin should be discontinued and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

Prior to administration, please read the Product Monograph for Omnipaque and the Important Safety Information About Iodinated Contrast Media, which is available by calling Customer Service 1 800 387 7146 or through an email request to canadainfo@ge.com.

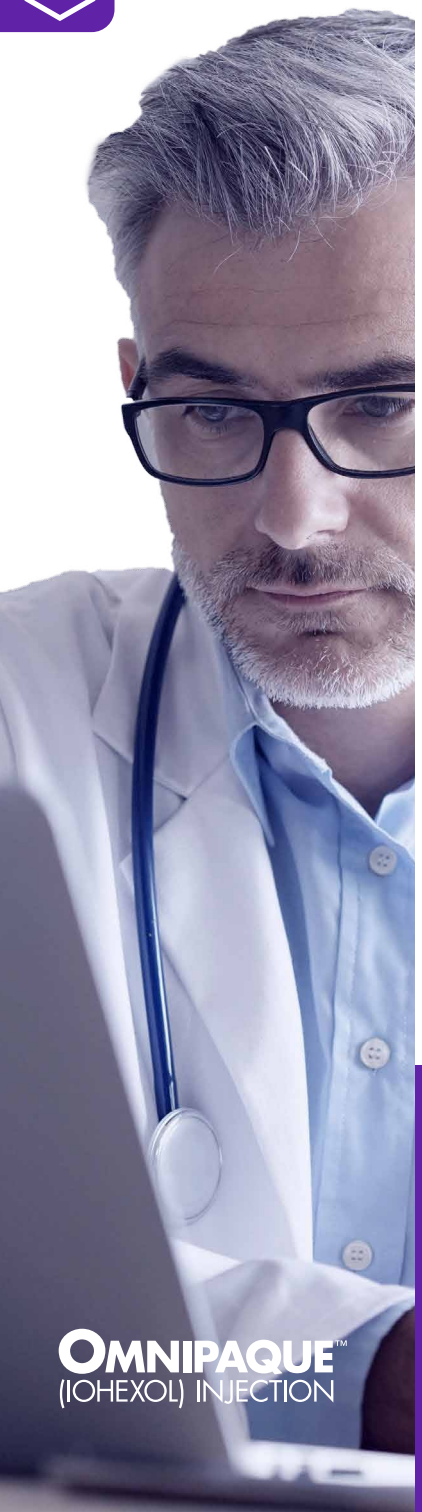
Reporting Side Effects

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1 800 654 0118 (option 2, then option 1), or email canadainfo@ge.com to request an adverse events form, or fax to 905 847 5849 to request an adverse events form.

Adverse reactions can also be reported to Health Canada as follows:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health- canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.



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