OMNIPAQUE- iohexol injection, solution
GE Healthcare

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use OMNIPAQUE safely and effectively. See full prescribing information for OMNIPAQUE.

OMNIPAQUE (iohexol) injection, for intrathecal, intra-arterial, intravenous, oral, rectal, intraarticular, or body cavity use
OMNIPAQUE (iohexol) oral solution
Initial U.S. Approval: 1985

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

Use only the iodine concentrations and presentations recommended for intrathecal procedures. Intrathecal administration 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. (2.2, 2.8, 5.1)

RECENT MAJOR CHANGES

Indications and Usage, Oral or Rectal Procedures (1.4)	4/2026

INDICATIONS AND USAGE

OMNIPAQUE is a radiographic contrast agent indicated for intrathecal, intra-arterial, intravenous, oral, rectal, intraarticular, and body cavity imaging procedures in adults and pediatric patients. (1)

DOSAGE AND ADMINISTRATION

- For each imaging procedure, specific dosage forms, concentrations, and presentations are recommended.
- Individualize the concentration and volume according to the specific dosing tables and accounting for factors such as age, body weight, and condition of the patient, and the equipment and imaging technique used. (2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9)
- See full prescribing information for complete dosing and administration information. (2)

DOSAGE FORMS AND STRENGTHS

- Injection: 140 mg iodine/mL, 180 mg iodine/mL, and 240 mg iodine/mL in single-dose vials/bottles; 300 mg iodine/mL and 350 mg iodine/mL in single-dose vials/bottles and imaging or pharmacy bulk package
- Oral Solution: 9 mg iodine/mL and 12 mg iodine/mL (3)

CONTRAINDICATIONS

- Hysterosalpingography 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. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: Life-threatening or fatal reactions can occur. Always have emergency equipment and trained personnel available. (5.3)
- Acute Kidney Injury: Acute injury including renal failure can occur. Minimize dose and maintain adequate hydration to minimize risk. (5.4)
- Cardiovascular Adverse Reactions: Hemodynamic disturbances including shock and cardiac arrest may occur during or after administration. (5.5)
- Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Individualize thyroid function monitoring based on risk factors such as prematurity. (5.9)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 1%) in adult patients

- Intrathecal: Headaches, pain including backache, neckache, stiffness and neuralgia, nausea, vomiting, dizziness
- Intra-arterial or intravenous: Pain, vision abnormalities (including blurred vision and photomas), headache, taste perversion, arrhythmias including premature ventricular contractions (PVCs) and premature atrial contractions (PACs), angina/chest pain, nausea
- Oral: Diarrhea, nausea, vomiting, abdominal pain, flatulence, headache
- Body Cavity: Pain, swelling, heat sensation (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 1-800-654-0118 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Lactation: A lactating woman may pump and discard breast milk for 10 hours after OMNIPAQUE administration. (8.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 4/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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

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FULL PRESCRIBING 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 *[see Dosage and Administration (2.2, 2.8)].* 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 *[see Warnings and Precautions (5.1)].*

1 INDICATIONS AND USAGE

1.1 Intrathecal Procedures‡

OMNIPAQUE is indicated for:

- Myelography and computerized tomography (CT) 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

1.2 Intra-arterial Procedures‡

OMNIPAQUE is indicated 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

1.3 Intravenous Procedures‡

OMNIPAQUE is indicated 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

1.4 Oral or Rectal Procedures‡

OMNIPAQUE is indicated for:

- Radiographic examination of the gastrointestinal (GI) tract by oral administration in adult patients and by oral or rectal administration in pediatric patients
- CT of the abdomen and pelvis by oral administration in adult and pediatric patients, in conjunction with intravenous administration of OMNIPAQUE

1.5 Intraarticular Procedures‡

OMNIPAQUE is indicated for:
- Arthrography in adults

1.6 Body Cavity Procedures‡

OMNIPAQUE is indicated for:
- Endoscopic retrograde pancreatography (ERP) and cholangiopancreatography (ERCP) in adults
- Herniography in adults
- Hysterosalpingography in adults
- Voiding cystourethrography (VCU) in pediatric patients

‡ Specific dosage forms, concentrations, and presentations of OMNIPAQUE are recommended for each type of imaging procedure *[see Dosage and Administrations (2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9) and Warnings and Precautions (5.1, 5.2)].*

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions
- Specific dosage forms, concentrations, and presentations of OMNIPAQUE are recommended for each type of imaging procedure *[see Dosage and Administration (2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9) and Warnings and Precautions (5.1, 5.2)].*
- Individualize the volume, strength, and rate of administration of OMNIPAQUE injection according to the specific dosing tables *[see Dosage and Administration (2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9)]*. Consider factors such as age, body weight, vessel size, blood flow rate within the vessel, anticipated pathology, degree and extent of opacification required, structures or area to be examined, disease processes affecting the patient, and equipment and technique to be employed.
- Hydrate patients before and after administration of OMNIPAQUE injection *[see Warnings and Precautions (5.4)].*
- Use aseptic technique for all handling and administration of OMNIPAQUE injection.
- Administer OMNIPAQUE injection at either body (37°C, 98.6°F) or room temperature (20°C to 25°C, 68°F to 77°F).
- Do not mix OMNIPAQUE injection with, or inject in intravenous lines containing, other drugs or total nutritional admixtures except when OMNIPAQUE injection is administered in an automated contrast injection system or contrast management system suitable for simultaneous injection of OMNIPAQUE injection and 0.9% Sodium Chloride Injection *[see Dosage and Administration (2.10, 2.11)].*
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Each container of OMNIPAQUE injection and OMNIPAQUE oral solution in single-dose containers are intended for one procedure only. Discard any unused portion.

2.2 Recommended Dosage for Intrathecal Procedures in Adults
- The recommended doses for intrathecal procedures in adults are shown in Table 1.
- Administer over 1 minute to 2 minutes.
- If sequential or repeat examinations are required, allow at least 48 hours for

clearance of the drug from the body before repeat administration; however, whenever possible, 5 days to 7 days is recommended.
- If CT myelography is performed, delay imaging by several hours to reduce the degree of contrast.

Table 1. Recommended Concentrations and Volumes of OMNIPAQUE Injection for Intrathecal Procedures in Adults

Imaging Procedure	Injection Type	Concentration (mg Iodine/mL)	Volume to Administer
Lumbar Myelography	Lumbar	180*	10 mL to 17 mL
		240*	7 mL to 12.5 mL
Thoracic Myelography	Lumbar Cervical	240*	6 mL to 12.5 mL
		300*	6 mL to 10 mL
Cervical Myelography	Lumbar	240*	6 mL to 12.5 mL
		300*	6 mL to 10 mL
	C1-2	180*	7 mL to 10 mL
		240*	6 mL to 12.5 mL
		300*	4 mL to 10 mL
Total Columnar Myelography	Lumbar	240*	6 mL to 12.5 mL
		300*	6 mL to 10 mL
CT Cisternography	Lumbar	180*	10 mL to 17 mL
		240*	7 mL to 12.5 mL

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)]*.

2.3 Recommended Dosage for Intra-arterial Procedures in Adults

The recommended doses for intra-arterial procedures in adults are shown in Table 2.

Table 2. Recommended Concentrations and Volumes of OMNIPAQUE Injection for Intra-arterial Procedures in Adults

Imaging Procedure	Concentration (mg Iodine/mL)	Volume to Administer per Single Injection for Selective Injection Sites	Maximum Cumulative Total Dose
Cardiac Ventriculography	350*	40 mL (Range of 30 mL to 60 mL) may be combined with selective coronary arteriography	250 mL
	300*	• Aorta (aortic arch, ascending aorta): 50 mL to 80 mL	290 mL

Aortography and Selective Visceral Arteriography		350*	• Abdominal aorta and its branches (celiac, mesenteric, hepatic, and splenic arteries): 30 mL to 60 mL • Renal arteries: 5 mL to 15 mL	250 mL
Aortic root and arch study when used alone		350*	50 mL (Range of 20 mL to 75 mL)	250 mL
Selective Coronary Arteriography		350*	5 mL (Range of 3 mL to 14 mL)	250 mL
Cerebral Arteriography		300*	• Common carotid artery: 6 mL to 12 mL • Internal carotid artery: 8 mL to 10 mL • External carotid artery: 6 mL to 9 mL • Vertebral artery: 6 mL to 10 mL	290 mL
Peripheral Arteriography	Aortofemoral Runoffs	300*	30 mL to 90 mL	290 mL
		350*	20 mL to 70 mL	250 mL
	Selective Arteriogram	300*	10 mL to 60 mL	290 mL
		350*	10 mL to 30 mL	250 mL
IA-DSA (head, neck,			• Aorta: 20 mL to 45 mL at 8 mL/sec to 20 mL/sec • Carotid artery: 5 mL to 10 mL at 3 mL/sec to 6 mL/sec • Femoral artery: 9 mL to 20 mL at 3 mL/sec to 6 mL/sec • Vertebral artery: 4 mL to 10 mL at 2	

abdominal, renal, and peripheral vessels)	140*	mL/sec to 8 mL/sec • Renal arteries: 6 mL to 12 mL at 3 mL/sec to 6 mL/sec • Other branches of aorta (includes subclavian, axillary, innominate, and iliac): 8 mL to 25 mL at 3 mL/sec to 10 mL/sec	250 mL

* Use single-dose containers or a 500 mL Pharmacy Bulk Package *[see Dosage and Administration (2.11)].*

2.4 Recommended Dosage for Intravenous Procedures in Adults

The recommended doses for intravenous procedures in adults are shown in Table 3.

Table 3. Recommended Concentrations and Volumes of OMNIPAQUE Injection for Intravenous Procedures in Adults

Imaging Procedure		**Concentration (mg Iodine/mL)**	**Volume to Administer**
Excretory Urography		300*	0.6 mL/kg to 1.2 mL/kg body weight (maximum dose is 102 mL)
		350*	
CT	Head	240*	120 mL to 250 mL by infusion
		300†	70 mL to 150 mL by rapid injection
		350†	80 mL by rapid injection
	Body	300†	50 mL to 200 mL by rapid injection
		350†	60 mL to 100 mL by rapid injection
Peripheral Venography (phlebography)		240*	20 mL to 150 mL per leg
		300*	40 mL to 100 mL per leg
IV-DSA (head, neck, abdominal, renal, and peripheral vessels)		350*	30 mL to 50 mL at 7.5 mL/sec to 30 mL/sec using a pressure injector Frequently three or more doses may be required; the maximum cumulative total dose is 250 mL

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)]*.
† Use single-dose containers, 500 mL Imaging Bulk Packages or Pharmacy Bulk Packages, or 150 mL single-dose bottles with an automated contrast injection system or contrast management system *[see Dosage and Administration (2.10, 2.11, 2.12)]*.

2.5 Recommended Dosage for Oral Procedures in Adults

Recommended Dosage for Radiographic Examination of the GI Tract in Adults

The recommended dose for radiographic examination of the GI tract in adults is 50 mL to 100 mL of OMNIPAQUE injection 350 mg iodine/mL administered undiluted orally.

Recommended Dosage for CT of the Abdomen and Pelvis in Conjunction with Intravenous Administration of OMINIPAQUE Injection in Adults

The recommended oral dose using diluted OMNIPAQUE injection or OMNIPAQUE oral solution and concurrent intravenous doses for CT of the abdomen and pelvis in adults are shown in Table 4.

Table 4. Recommended Concentrations and Volumes of Diluted OMNIPAQUE Injection or OMNIPAQUE Oral Solution for Oral Administration and Concurrent Intravenous OMNIPAQUE Injection for CT of the Abdomen and Pelvis in Adults

Concentration (mg Iodine/mL)	Volume to Administer	Administration Instructions
Oral Dose Using Diluted OMNIPAQUE Injection		
6 mg Iodine/mL to 12 mg Iodine/mL of Diluted OMNIPAQUE Injection*	500 mL to 1,000 mL	• Administer the oral dose all at once or over a period of up to 45 minutes if there is difficulty in consuming the required volume. • Use a higher iodine concentration of the diluted product if a smaller volume needs to be administered (see Table 5).
Oral Dose Using OMNIPAQUE Oral Solution		
9 mg Iodine/mL or 12 mg Iodine/mL of OMNIPAQUE Oral Solution	500 mL to 1,000 mL	Administer the oral dose all at once or over a period of up to 45 minutes if there is difficulty in consuming the required volume.
Intravenous Dose of OMNIPAQUE injection in Conjunction with Oral Administration		
300†	100 mL to 150 mL	Administer up to 40 minutes AFTER consumption of the oral dose.

* See Table 5 for dilution instructions of OMNIPAQUE injection
† Use single-dose containers, 500 mL Imaging or Pharmacy Bulk Packages, or 150 mL single-dose bottles with an automated contrast injection system or contrast management system *[see Dosage and Administration (2.10, 2.11, 2.12)]*.

Preparation of Diluted OMNIPAQUE Injection for Oral Administration for CT of the Abdomen and Pelvis in Adults

- Prepare the diluted OMNIPAQUE injection in water, carbonated beverage, milk, or juice just prior to administration according to Table 5.
- Discard any unused portion after the procedure.

Table 5. Volumes of OMNIPAQUE Injection and Added Liquid to Dilute OMNIPAQUE Injection for Oral Administration for CT of the Abdomen in Adults

Concentration of Diluted OMNIPAQUE injection (mg iodine/mL)	Dilution Method 1		Dilution Method 2		Dilution Method 3	
	Volume of OMNIPAQUE 240 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)	Volume of OMNIPAQUE 300 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)	Volume of OMNIPAQUE 350 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)
6	25	975	20	980	17	983
9	38	962	30	970	26	974
12	50	950	40	960	35	965

* Use water, carbonated beverage, milk, or juice.

2.6 Recommended Dosage for Intraarticular Procedures in Adults

- The recommended doses for intraarticular procedures in adults are shown in Table 6.
- Use passive or active manipulation to disperse the medium throughout the joint space.

Table 6. Recommended Concentrations and Volumes of OMNIPAQUE Injection for Intraarticular Procedures in Adults

Imaging Procedure	Location	Concentration (mg Iodine/mL)	Volume to Administer	Double Contrast/Single Contrast
Arthrography	Knee	240*	5 mL to 15 mL	Lower volumes recommended for double-contrast examinations; higher volumes recommended for single-contrast examinations.
		300*	5 mL to 15 mL	
		350*	5 mL to 10 mL	
	Shoulder	300*	10 mL	
	Temporomandibular	300*	0.5 mL to 1 mL	

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)]*.

2.7 Recommended Dosage for Body Cavity Procedures in Adults

- The recommended doses for body cavity procedures in adults are shown in Table 7.
- Volume to administer may vary depending on individual anatomy and/or disease

state.

Table 7. Recommended Concentrations and Volumes of OMNIPAQUE Injection for Body Cavity Procedures in Adults

Imaging Procedure	Concentration (mg Iodine/mL)	Volume to Administer	Route of Administration
Endoscopic retrograde pancreatography (ERP) and cholangiopancreatography (ERCP)	240*	10 mL to 50 mL	Intraductal
Herniography	240*	15 mL to 20 mL	Intraperitoneal
	300*		
Hysterosalpingography	240*	50 mL	Intrauterine

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)].*

2.8 Recommended Dosage for Intrathecal, Intra-arterial, and Intravenous Procedures in Pediatric Patients

Recommended Dosage for Intrathecal Procedures in Pediatric Patients Aged 2 Weeks and Older

- Recommended doses based on age for intrathecal procedures in pediatric patients aged 2 weeks and older are shown in Table 8.
- Administer over 1 minute to 2 minutes.
- If sequential or repeat examinations are required, allow at least 48 hours for clearance of the drug from the body before repeat administration; however, whenever possible, 5 days to 7 days is recommended.
- If CT myelography is performed, delay imaging by several hours to reduce the degree of contrast.

Table 8: Recommended Concentrations and Volumes of OMNIPAQUE Injection Based on Age for Intrathecal Procedure in Pediatric Patients Aged 2 Weeks and Older

Imaging Procedure	Injection Type	Age	Concentration (mg Iodine/mL)	Volume to Administer
• Myelography ◦ Lumbar ◦ Thoracic ◦ Cervical ◦ Total Columnar • CT cisternography	Lumbar	2 weeks up to 3 months	180*	2 mL to 4 mL
		3 months up to 36 months		4 mL to 8 mL
		3 years up to 7 years		5 mL to 10 mL
		7 years up to 13 years		5 mL to 12 mL
		13 years to 18 years		6 mL to 15 mL

* Use single-dose containers.

Recommended Dosage for Intra-arterial Procedures in Pediatric Patients

The recommended doses for intra-arterial procedures in pediatric patients are shown in Table 9.

Table 9. Recommended Concentrations and Volumes of OMNIPAQUE Injection per Body Weight for Intra-arterial Procedures in Pediatric Patients

Imaging Procedure	Concentration (mg Iodine/mL)	Volume per Body Weight to Administer per Single Injection	Maximum Cumulative Volume
Cardiac Ventriculography	300*	1.75 mL/kg (Range of 1.5 mL/kg to 2 mL/kg)	6 mL/kg up to a total volume of 290 mL
	350*	1.25 mL/kg (Range of 1 mL/kg to 1.5 mL/kg)	5 mL/kg up to a total volume of 250 mL
Aortography (aortic root, aortic arch, and descending aorta)	350*	1 mL/kg	5 mL/kg up to a total volume of 250 mL
Pulmonary Angiography	350*	1 mL/kg	5 mL/kg up to a total volume of 250 mL

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)].*

Recommended Dosage for Intravenous Procedures in Pediatric Patients

The recommended doses for intravenous procedures in pediatric patients are shown in Table 10.

Table 10. Recommended Concentrations and Volumes of OMNIPAQUE Injection per Body Weight for Intravenous Procedures in Pediatric Patients

Imaging Procedure	Concentration (mg Iodine/mL)	Volume per Body Weight to Administer
Excretory Urography	300*	0.5 mL/kg to 3 mL/kg (Maximum single dose: 116 mL)
CT of the Head and Body	240*	1 mL/kg to 2 mL/kg (with maximum 3 mL/kg) (Maximum single dose: 116 mL)
	300†	

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)].*

† Use single-dose containers, 500 mL Imaging or Pharmacy Bulk Packages, or 150

mL single-dose bottles with an automated contrast injection system or contrast management system *[see Dosage and Administration (2.10, 2.11, 2.12)]*.

2.9 Recommended Dosage for Oral or Rectal and Body Cavity Procedures in Pediatric Patients

Recommended Dosage for Radiographic Examination of the GI Tract in Pediatric Patients

- The recommended doses for radiographic examination of the GI tract are shown in Table 11.
- Administer orally or rectally.

Table 11. Recommended Concentrations and Volumes of OMNIPAQUE Injection Based on Age for Radiographic Examination of the GI Tract in Pediatric Patients

Age	Concentration (mg iodine/mL)	Oral Volume	Rectal Volume
Less than 3 months	180*	5 mL to 30 mL	May be a larger volume than the volume given orally (up to 300 mL)
3 months to 3 years	180*, 240*, or 300*	Up to 60 mL	
4 years to 10 years		Up to 80 mL	
Greater than 10 years		Up to 100 mL	

* Use single-dose containers or 500 mL Pharmacy Bulk Packages *[see Dosage and Administration (2.11)]*.

Recommended Dosage for CT of the Abdomen and Pelvis in Conjunction with Intravenous Administration of OMNIPAQUE in Pediatric Patients

The recommended oral dose using diluted OMNIPAQUE injection or OMNIPAQUE oral solution and concurrent intravenous dose for CT of the abdomen and pelvis in pediatric patients are shown in Table 12.

Table 12. Recommended Concentrations and Volumes of Diluted OMNIPAQUE Injection or OMNIPAQUE Oral Solution for Oral Administration and Concurrent Intravenous OMNIPAQUE Injection for CT of the Abdomen and Pelvis in Pediatric Patients

Concentration (mg Iodine/mL)	Volume to Administer	Administration Instructions	Maximum Dose by Age or Body Weight
Oral Dose Using Diluted OMNIPAQUE Injection			
9 mg Iodine/mL to 21 mg Iodine/mL of Diluted OMNIPAQUE Injection*		• Administer the oral dose all at once or over a period of up to 45 minutes if there is difficulty in consuming the	• less than 3 years old: 5

	180 mL to 750 mL	required volume. • Use a higher iodine concentration of the diluted product if a smaller volume needs to be administered (see Table 13).	grams iodine • 3 years old to 18 years old: 10 grams iodine
Oral Dose Using OMNIPAQUE Oral Solution			
9 mg Iodine/mL or 12 mg Iodine/mL of OMNIPAQUE Oral Solution	180 mL to 750 mL	Administer the oral dose all at once or over a period of up to 45 minutes if there is difficulty in consuming the required volume.	• less than 3 years old: 5 grams iodine • 3 years old to 18 years old: 10 grams iodine
Intravenous Dose in Conjunction with Oral Administration			
240† or 300†	2 mL/kg body weight (with a range of 1 mL/kg to 2 mL/kg)	Administer up to 60 minutes AFTER consumption of the oral dose.	3 mL/kg (maximum single dose: 116 mL)

* See Table 13 for dilution instructions of OMNIPAQUE injection

† Use single-dose containers, 500 mL Imaging or Pharmacy Bulk Packages, or 150 mL single-dose bottles with an automated contrast injection system or contrast management system *[see Dosage and Administration (2.10, 2.11, 2.12)]*.

Preparation of Diluted OMNIPAQUE Injection for Oral Administration for CT of the Abdomen and Pelvis in Pediatric Patients

- Prepare the diluted OMNIPAQUE injection in water, carbonated beverage, milk, infant formula, or juice just prior to administration according to Table 13.
- Discard any unused portion after the procedure.

Table 13. Volumes of OMNIPAQUE Injection and Added Liquid to Dilute OMNIPAQUE Injection for Oral Administration for CT of the Abdomen and Pelvis in Pediatric Patients

Concentration of Diluted OMNIPAQUE injection (mg iodine/mL)	Dilution Method 1		Dilution Method 2		Dilution Method 3	
	Volume of OMNIPAQUE 240 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)	Volume of OMNIPAQUE 300 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)	Volume of OMNIPAQUE 350 mg Iodine/mL (mL)	Volume of Added Liquid* (mL)
9	38	962	30	970	26	974
12	50	950	40	960	35	965
15	63	937	50	950	43	957
18	75	925	60	940	52	948
21	88	912	70	930	60	940

* Use water, carbonated beverage, milk, infant formula, or juice.

Recommended Dosage for Voiding Cystourethrography in Pediatric Patients

- Voiding cystourethrography (VCU) can be performed in conjunction with excretory urography *[see Dosage and Administration (2.8)]*.
- The concentration of diluted OMNIPAQUE injection may vary depending upon the patient's size and age and with the technique and equipment used.
- Volume ranges of diluted OMNIPAQUE injection 50 mg iodine/mL and 100 mg iodine/mL are shown in Table 14.
- Dilute OMNIPAQUE injection with Sterile Water for Injection according to Table 15, utilizing aseptic technique, just prior to use.
- Discard any unused portion after the procedure.

Table 14. Volume Ranges of Diluted OMNIPAQUE Injection for VCU in Pediatric Patients

Concentration of Diluted OMNIPAQUE Injection* (mg iodine/mL)	Volume to Administer
50	50 mL to 600 mL by intravesical administration
100	50 mL to 300 mL by intravesical administration

* See Table 15 below for dilution instructions of OMNIPAQUE injection.

Table 15. Volumes of OMNIPAQUE Injection and Sterile Water for Injection to Dilute OMNIPAQUE Injection for VCU in Pediatric Patients

Concentration of Diluted OMNIPAQUE injection (mg iodine/mL)	Dilution Method 1		Dilution Method 2		Dilution Method 3	
	Volume of OMNIPAQUE 240 mg Iodine/mL (mL)	Volume of Sterile Water for Injection (mL)	Volume of OMNIPAQUE 300 mg Iodine/mL (mL)	Volume of Sterile Water for Injection (mL)	Volume of OMNIPAQUE 350 mg Iodine/mL (mL)	Volume of Sterile Water for Injection (mL)
50	100	380	100	500	100	600
60	100	300	100	400	100	483
70	100	243	100	330	100	400
80	100	200	100	275	100	338
90	100	167	100	233	100	289
100	100	140	100	200	100	250

2.10 Directions for Use of the 500 mL Bottles of OMNIPAQUE Injection 300 mg Iodine/mL and 350 mg Iodine/mL as Imaging Bulk Package

- OMNIPAQUE injection 300 mg iodine/mL and OMNIPAQUE injection 350 mg iodine/mL in 500 mL bottles may be used as an Imaging Bulk Package (IBP) for intravenous use *[see Dosage and Administration (2.4, 2.8)]*.

- When used as an IBP, check the appropriate box on the container label to indicate that the selected container is to be utilized as an Imaging Bulk Package. This container is for use only with an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with this contrast agent in this IBP. See device labeling for information on devices indicated for use with this IBP and techniques to help assure safe use.
- Use the OMNIPAQUE IBP and 0.9% Sodium Chloride Injection USP in a room designated for radiological procedures that involve administration of a contrast agent.
- Using aseptic technique, penetrate the container closure only one time with a suitable sterile component of the automated contrast injection system, contrast management system, or contrast media transfer set cleared for use with the OMNIPAQUE IBP.
- If 0.9% Sodium Chloride Injection USP is used with the OMNIPAQUE IBP, prepare the 0.9% Sodium Chloride Injection USP sterile port in accordance with the dosage and administration section of its approved prescribing information and affix the saline tag provided with the OMNIPAQUE IBP on the 0.9% Sodium Chloride Injection USP container.
- Once the OMNIPAQUE IBP and 0.9% Sodium Chloride Injection containers are punctured, do not remove them from the work area during the entire period of use. Maintain the OMNIPAQUE IBP in an inverted position such that container contents are in continuous contact with the dispensing set.
- After the container closure is punctured, if the integrity of the OMNIPAQUE IBP, the 0.9% Sodium Chloride Injection, and the delivery system cannot be assured through direct continuous supervision, discard the IBP, 0.9% Sodium Chloride Injection USP, and all associated disposables for the contrast media transfer set.
- A maximum time from initial puncture is 8 hours. Discard any unused portion.

2.11 Directions for Use of the 500 mL Bottles of OMNIPAQUE Injection 300 mg Iodine/mL and 350 mg Iodine/mL as Pharmacy Bulk Package

- OMNIPAQUE injection 300 mg iodine/mL and OMNIPAQUE injection 350 mg iodine/mL in 500 mL bottles contain many single doses and may be used as a Pharmacy Bulk Package (PBP).
- When used as a PBP, check the appropriate box on the container label to indicate that the selected container is to be utilized as a Pharmacy Bulk Package. This container is not for direct infusion; it is for use in pharmacy admixture service to dispense aliquots using a suitable dispensing set under a laminar flow hood or equivalent clean air compounding area using aseptic technique.
- Penetrate the container closure only one time, utilizing a suitable transfer device and aseptic technique.
- The withdrawal of container contents should be accomplished without delay. However, should this not be possible, a maximum time of 8 hours from initial closure entry is permitted to complete fluid transfer operations.
- Do not remove the container from the aseptic area during the entire 8-hour period.
- The temperature of the container should not exceed 37°C (98.6°F), after the closure has been entered.
- Discard any unused portion after 8 hours from the initial closure entry.

2.12 Directions for Use of the 150 mL Bottles of OMNIPAQUE Injection 300 mg Iodine/mL and 350 mg Iodine/mL with an Automated Contrast Injection

System or Contrast Management System

- OMNIPAQUE injection 300 mg iodine/mL and OMNIPAQUE injection 350 mg iodine/mL in 150 mL bottles may be used with a contrast media management system cleared for use with OMNIPAQUE injection 300 mg iodine/mL and 350 mg iodine/mL in 150 mL bottles.
- See device labeling for information on device indications, instructions for use, and techniques to help assure safe use.
- Using aseptic technique, penetrate the container closure only one time with a suitable sterile component of the contrast media management system cleared for use with OMNIPAQUE 300 mg iodine/mL and 350 mg iodine/mL in 150 mL bottles.
- Once the container is punctured, do not remove the bottle from the work area during the entire period of use.
- Maximum use time is 4 hours after initial puncture.
- Each bottle is for one procedure only. Discard unused portion.

3 DOSAGE FORMS AND STRENGTHS

Injection and Oral Solution: Colorless to pale yellow solution available in the following presentations:

Dosage Form	Concentration (mg of iodine/mL)	Package Size	Package Type
Injection	140	50 mL	Single-Dose Bottle
	180	10 mL	Single-Dose Vial
	240	10 mL and 20 mL	Single-Dose Vial
		50 mL and 100 mL	Sigle-Dose Bottle
	300	10 mL	Single-Dose Vial
		30 mL, 50 mL, 100 mL, 125 mL, and 150 mL	Single-Dose Bottle
		500 mL*	Imaging or Pharmacy Bulk Package
	350	50 mL, 75 mL, 100 mL, 125 mL, 150 mL, and 200 mL	Single-Dose Bottle
		500 mL*	Imaging or Pharmacy Bulk Package
Oral Solution	9	500 mL	Single-Dose Bottle
	12	500 mL	Single-Dose Bottle

* OMNIPAQUE injection 300 mg iodine/mL and OMNIPAQUE injection 350 mg iodine/mL in bottles of 500 mL can be used as either an Imaging Bulk Package or a Pharmacy Bulk Package *[see Dosage and Administration (2.10, 2.11)].*

4 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.

5 WARNINGS AND PRECAUTIONS

5.1 Risks Associated with Intrathecal Administration of OMNIPAQUE Injection 140 mg Iodine/mL and 350 mg Iodine/mL

Use only the iodine concentrations and presentations recommended for intrathecal procedures *[see Dosage and Administration (2.2, 2.8)].* Intrathecal administration of OMNIPAQUE of a wrong iodine concentration, even if inadvertent, can cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.

5.2 Risks Associated with Parenteral Administration of OMNIPAQUE Oral Solution

Adverse reactions such as hemolysis may occur if OMNIPAQUE oral solution is administered intravenously or intraarterially due to low osmolality *[see Description (11)]*. OMNIPAQUE oral solution is for oral use only.

5.3 Hypersensitivity Reactions

OMNIPAQUE can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis. Manifestations include respiratory arrest, laryngospasm, bronchospasm, angioedema, and shock. 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 (i.e., bronchial asthma, drug, or food allergies) or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both their incidence and severity.

Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents and always have emergency resuscitation equipment and trained personnel available prior to OMNIPAQUE administration. Monitor all patients for hypersensitivity reactions.

5.4 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 the lowest necessary dose of OMNIPAQUE in patients with renal impairment. Adequately hydrate patients prior to and following parenteral administration of OMNIPAQUE. Do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration.

5.5 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 injection or five to ten minutes later, with cardiovascular disease as the main aggravating factor. Cardiac decompensation, serious arrhythmias, and myocardial ischemia or infarction can occur during coronary arteriography and ventriculography.

Based on clinical literature, reported deaths from the administration of iodinated contrast agents range from 6.6 per million (0.00066%) to 1 in 10,000 (0.01%). Use the lowest necessary dose of OMNIPAQUE in patients with congestive heart failure and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

5.6 Thromboembolic Events

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiography procedures with iodinated contrast agents including OMNIPAQUE. During these procedures, increased thrombosis and activation of the complement system occurs. Risk factors for thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications.

To minimize thromboembolic events, use meticulous angiographic techniques, and minimize the length of the procedure. Avoid blood remaining in contact with syringes containing OMNIPAQUE, which increases the risk of clotting. Avoid angiocardiography in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

5.7 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 intravenous or intra-arterial placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

5.8 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 such patients before use of OMNIPAQUE.

5.9 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 pediatric patients 0 to 3 years of age.

Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after ICM exposure. Pediatric patients with congenital cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures.

An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to ICM, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

5.10 Hypertensive Crisis in Patients with Pheochromocytoma

Hypertensive crisis has occurred after the use of iodinated contrast agents in patient with pheochromocytoma. Monitor patients when administering OMNIPAQUE intravenously or intra-arterially if pheochromocytoma or catecholamine-secreting paragangliomas are suspected. Inject the minimum amount of contrast necessary, assess the blood pressure throughout the procedure, and have measures for treatment of a hypertensive crisis readily available.

5.11 Sickle Cell Crisis in Patients with Sickle Cell Disease

Iodinated contrast agents when administered intravenously or intra-arterially may promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following OMNIPAQUE administration and use OMNIPAQUE only if the necessary imaging information cannot be obtained with alternative imaging modalities.

5.12 Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions (SCAR) 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 (SJS/TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of contrast agents; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering OMNIPAQUE to patients with a history of a severe cutaneous adverse reaction to OMNIPAQUE.

5.13 Interference with Laboratory Test

OMNIPAQUE can interfere with protein-bound iodine test *[see Drug Interactions (7.2)].*

5.14 Increased Risk of Seizures with Intrathecal Procedures

Focal and generalized motor seizures have been reported after intrathecal use of iodinated contrast agents. In several of the cases, higher than recommended doses were administered.

Use of medications that may lower the seizure threshold (phenothiazine derivatives, including those used for their antihistaminic properties; tricyclic antidepressants; MAO inhibitors; CNS stimulants; analeptics; antipsychotic agents) should be carefully evaluated. Consider discontinuing these agents at least 48 hours before and for at least 24 hours following intrathecal administration of OMNIPAQUE.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the

labeling:

- Risks Associated with Intrathecal Administration of OMNIPAQUE Injection 140 mg Iodine/mL and 350 mg Iodine/mL *[see Warnings and Precautions (5.1)]*
- Risks Associated with Parenteral Administration of OMNIPAQUE Oral Solution *[see Warnings and Precautions (5.2)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*
- Acute Kidney Injury *[see Warnings and Precautions (5.4)]*
- Cardiovascular Adverse Reactions *[see Warnings and Precautions (5.5)]*
- Thromboembolic Events *[see Warnings and Precautions (5.6)]*
- Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age *[see Warnings and Precautions (5.9)]*
- Severe Cutaneous Adverse Reactions *[see Warnings and Precautions (5.12)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Intrathecal Administration

Adults

Adverse reactions (≥1%) in 1,531 adult patients following intrathecal administration of OMNIPAQUE in clinical trials are presented in Table 16.

Table 16. Adverse Reactions (≥1%) in in Adult Patients Following Intrathecal Administration of OMNIPAQUE in Clinical Trials

System Organ Class	Adverse Reaction	Incidence N=1,531
Nervous system disorders	Headaches	18%
Musculoskeletal and connective tissue disorders	Pain including backache, neckache, stiffness, neuralgia	8%
Gastrointestinal disorders	Nausea	6%
	Vomiting	3%
Nervous System disorders	Dizziness	2%

Other adverse reactions (<1%) were:

Ear and labyrinth disorders: tinnitus, vertigo

Eye disorders: photophobia

General disorders and administration site conditions: sensation of heat

Metabolism and nutrition disorders: loss of appetite

Musculoskeletal and connective tissue disorders: feeling of heaviness

Nervous system disorders: drowsiness, hypertonia, neuralgia, neurological changes, paresthesia, syncope

Renal and urinary disorders: difficulty in micturition

Skin and subcutaneous tissue disorders: sweating

Vascular disorders: hypertension, hypotension

Pediatric Patients

The adverse reactions reported in pediatric patients following intrathecal administration of OMNIPAQUE were generally similar to those reported in adults. A total of 152 pediatric patients were administered OMNIPAQUE 180 mg iodine/mL intrathecally by lumbar puncture for pediatric myelography in clinical trials. Adverse reactions (≥1%) are presented in Table 17.

Table 17. Adverse Reactions (≥1%) in Pediatric Patients Following Intrathecal Administration of OMNIPAQUE 180 mg iodine/mL by Lumbar Puncture for Myelography in Clinical Trials

System Organ Class	Adverse Reaction	Incidence N=152
Nervous system disorders	Headache	9%
Gastrointestinal disorders	Vomiting	6%
Musculoskeletal and connective tissue disorders	Backache	1.3%

Other adverse reactions (<1%) were:

Gastrointestinal disorders: stomachache

General disorders and administration site conditions: fever

Nervous system disorders: neurological changes

Psychiatric disorders: visual hallucination

Skin and subcutaneous tissue disorders: hives

Intra-arterial or Intravenous Administration

Adults

Adverse reactions (≥1%) in 1,485 adult patients following intra-arterial or intravenous administration of OMNIPAQUE in clinical trials are presented in Table 18.

Table 18. Adverse Reactions (≥1%) in Adult Patients Following Intra-arterial or Intravenous Administration of OMNIPAQUE in Clinical Trials

System Organ Class	Adverse Reaction	Incidence (N=1,485)
Cardiac disorders	Arrhythmias including PVCs and PACs	2%
Nervous system disorders	Pain	3%
	Vision abnormalities including blurred vision and photomas	2%
	Taste perversion	1%

Gastrointestinal disorders	Nausea	2%

Other adverse reactions (<1%) were:

Cardiac disorders: hypotension, cardiac failure, asystole, bradycardia, tachycardia, vasovagal reaction

Respiratory, thoracic and mediastinal disorders: dyspnea, rhinitis, coughing, laryngitis

Gastrointestinal disorders: vomiting, diarrhea, dyspepsia, cramp, dry mouth

General disorders and administration site conditions: fever, shivering

Nervous system disorders: cerebral infarction, convulsion, hemiparesis, motor and speech dysfunction, nystagmus, paresthesia, somnolence, transient ischemic attack, vertigo including dizziness and lightheadedness

Musculoskeletal and connective tissue disorders: still neck

Skin and subcutaneous tissue disorders: urticaria, abscess, pruritus, purpura

Psychiatric disorders: anxiety, syncope

Pediatric Patients

Adverse reactions reported in pediatric patients following intra-arterial or intravenous administration of OMNIPAQUE were generally similar in quality and frequency to those reported in adults. A total of 391 pediatric patients in clinical trials were administered OMNIPAQUE 240 mg iodine/mL, 300 mg iodine/mL, or 350 mg iodine/mL by intra-arterial or intravenous injection for pediatric cardiac ventriculography, excretory urography, and CT head imaging.

Adverse reactions (≥1%) were vomiting (2%) and nausea (1%).

Other adverse reactions (<1%) were:

Cardiac disorders: Ventricular tachycardia, 2:1 heart block, hypertension, anemia

General disorders and administration site conditions: Pain, fever

Nervous system disorders: Convulsion, taste abnormality

Respiratory, thoracic and mediastinal disorders: Congestion, apnea

Endocrine disorders: Hypoglycemia

Skin and subcutaneous tissue disorders: Rash

Oral or Rectal Administration for Examination of the Gastrointestinal Tract

Adults

A total of 54 adult patients were administered undiluted OMNIPAQUE 350 mg iodine/mL by oral route for radiographic examination of the gastrointestinal tract in clinical trials. Adverse reactions (≥1%) are presented in Table 19.

Table 19. Adverse Reactions (≥1%) in Adult Patients Following Oral Administration of Undiluted OMNIPAQUE 350 mg Iodine/mL in

Clinical Trials

System Organ Class	Adverse Reaction	Incidence N=54
Gastrointestinal disorders	Diarrhea	42%
	Nausea	15%
	Vomiting	11%
	Abdominal Pain	7%
	Flatulence	2%
Nervous system disorders	Headache	2%

Pediatrics Patients

A total of 58 pediatric patients were administered OMNIPAQUE by oral or rectal administration in clinical trials. Adverse reactions (≥1%) are presented in Table 20.

Table 20. Adverse Reactions (≥1%) in Pediatric Patients Following Oral or Rectal Administration of OMNIPAQUE in Clinical Trials

System Organ Class	Adverse Reaction	Incidence N=58
Gastrointestinal disorders	Diarrhea	36%
	Vomiting	9%
	Nausea	5%
	Abdominal pain	2%
General disorders and administration site conditions	Fever	5%
Skin and subcutaneous tissue disorders	Urticaria	2%
Vascular disorders	Hypotension	2%

Oral Administration for CT of the Abdomen in Conjunction with Intravenous Administration

Adults

A total of 44 adult patients received diluted OMNIPAQUE (4-9 mg iodine/mL) by oral route in conjunction with intravenously injected OMNIPAQUE 300 mg iodine/mL for CT examination of the abdomen in clinical trials. Adverse reactions (≥1%) were limited to a single report of vomiting (2.3%).

Pediatric Patients

A total of 69 pediatric patients received diluted OMNIPAQUE (9-29 mg iodine/mL) by oral route in conjunction with intravenously administered OMNIPAQUE 240 mg iodine/mL or OMNIPAQUE 300 mg iodine/mL for CT examination of the abdomen in clinical trials. Adverse reactions (≥1%) were limited to a single report of vomiting (1.4%).

Intraarticular Administration

Arthrography in Adults

A total of 285 adult patients received OMNIPAQUE 240 mg iodine/mL, 300 mg iodine/mL, or 350 mg iodine/mL for various body cavity examinations in clinical trials. The most frequent adverse reactions (≥1%) were administration site pain (26%) and swelling (22%) in arthrography. Patients also experienced heat (7%).

Body Cavity Use

VCU in Pediatric Patients

No new adverse reactions associated with the use of OMNIPAQUE for VCU procedures were reported in 51 pediatric patients studied.

6.2 Post-marketing Experience

The following adverse reactions have been identified during post-approval use of OMNIPAQUE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General

Immune system disorders: Hypersensitivity reactions, anaphylactic or anaphylactoid reactions, anaphylactic or anaphylactoid shock including life-threatening or fatal anaphylaxis

General disorders and administration site conditions: Pyrexia, chills, pain and discomfort, asthenia, administration site conditions including extravasation

Intrathecal Administration

Nervous system disorders: Meningism, aseptic meningitis, seizures or status epilepticus, disorientation, coma, depressed or loss of consciousness, transient contrast-induced toxic encephalopathy (including amnesia, hallucination, paralysis, paresis, speech disorder, aphasia, dysarthria), restlessness, tremors, hypoesthesia

Musculoskeletal and connective tissue disorders: Pain, muscle spasms or spasticity

Psychiatric disorders: Confusional state, agitation, anxiety

Eye disorders: Transient visual impairment including cortical blindness

Renal and urinary disorders: Acute kidney injury

Intra-arterial or Intravenous Administration

Cardiac disorders: Severe cardiac complications (including cardiac arrest, cardiopulmonary arrest), shock, peripheral vasodilatation, palpitations, vasospasm including spasm of coronary arteries, myocardial infarction, syncope, cyanosis, pallor, flushing, chest pain

Vascular disorders: Vasospasm and thrombophlebitis following intravenous injection

Blood and lymphatic system disorders: Neutropenia

Nervous system disorders: Disorientation, coma, depressed or loss of consciousness, transient contrast-induced toxic encephalopathy (including amnesia, hallucination,

paralysis, paresis, speech disorder, aphasia, dysarthria), restlessness, tremors, hypoesthesia

Psychiatric disorders: Confusional state, agitation

Eye disorders: Eye irritation or itchiness, periorbital edema, ocular or conjunctival hyperemia, lacrimation

Renal and urinary disorders: Acute kidney injury, toxic nephropathy (CIN), transient proteinuria, oliguria or anuria, increased serum creatinine

Gastrointestinal disorders: Abdominal pain, pancreatitis aggravated, salivary gland enlargement

Endocrine disorders: Hyperthyroidism, hypothyroidism

Respiratory, thoracic and mediastinal disorders: Respiratory distress, respiratory failure, pulmonary edema, bronchospasm, laryngospasm, throat irritation, throat tightness, laryngeal edema, wheezing, chest discomfort, asthmatic attack

Skin and subcutaneous tissue disorders: Contrast media reactions range from mild (e.g., pleomorphic rashes, drug eruption, erythema and skin discoloration, blisters, hyperhidrosis, angioedema, localized areas of edema) to severe (e.g., Stevens-Johnson syndrome and toxic epidermal necrolysis [SJS/TEN], bullous or exfoliative dermatitis, acute generalized exanthematous pustulosis [AGEP] and drug reaction with eosinophilia and systemic symptoms [DRESS])

Oral Administration

Gastrointestinal disorders: Dysphagia, abdominal pain

Body Cavity Administration

Gastrointestinal disorders: Pancreatitis

Musculoskeletal and connective tissue disorders: Arthritis (arthrography)

Hysterosalpingography: Injection of OMNIPAQUE for hysterosalpingography is associated with immediate, transient pain. Monitor injection pressure and volume instilled to minimize pain and to avoid disruptive distention of the uterus and fallopian tubes. Fluoroscopic monitoring is recommended.

Nervous system disorders: Pain (49%), somnolence and fever each with an individual incidence of 3%

Gastrointestinal disorders: Nausea (3%)

7 DRUG INTERACTIONS

7.1 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, OMNIPAQUE administration in patients with an eGFR between 30 and 60 mL/min/1.73

m^2; 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

OMNIPAQUE may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE.

7.2 Drug-Laboratory Test Interactions

Protein-Bound Iodine Test

Iodinated contrast agents, including OMNIPAQUE, will temporarily increase protein-bound iodine in blood. Do not perform protein-bound iodine test for at least 16 days following administration of OMNIPAQUE. However, thyroid function tests that do not depend on iodine estimation, e.g., T_3 resin uptake or direct thyroxine assays, are not affected.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Hysterosalpingography is contraindicated in pregnant women due to the potential risk to the fetus from an intrauterine procedure *[see Contraindications (4)].* There are no data with iohexol use in pregnant women to inform any drug-associated risks. Iohexol crosses the placenta and reaches fetal tissues in small amounts *(*see *Data)*. In animal reproduction studies, no developmental toxicity occurred with intravenous iohexol administration to rats and rabbits at doses up to 0.4 (rat) and 0.5 (rabbit) times the maximum recommended human intravenous dose (*see Data*).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

Literature reports show that intravenously administered iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth.

Animal Data

Iohexol was neither embryotoxic nor teratogenic in either rats or rabbits at the following dose levels tested: 1.0, 2.0, 4.0 g iodine/kg in rats, administered intravenously to 3 groups of 25 dams once daily during days 6 through 15 of pregnancy; 0.3, 1.0, 2.5 g iodine/kg in rabbits, administered intravenously to 3 groups of 18 rabbits dosed once a day during days 6 through 18 of pregnancy.

8.2 Lactation

Risk Summary

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; however, lactation studies have not been conducted with oral, intrathecal, or intracavity administration of iohexol. There is no information on the effects of the drug on the breastfed infant or on milk production. Iodinated contrast agents are excreted unchanged in human milk in very low amounts with poor absorption from the gastrointestinal tract of a breastfed infant. Exposure to iohexol to a breastfed infant can be minimized by temporary discontinuation of breastfeeding (see Clinical Considerations). The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OMNIPAQUE and any potential adverse effects on the breastfed infant from OMNIPAQUE or from the underlying maternal condition.

Clinical Considerations

Interruption of breastfeeding after exposure to iodinated contrast agents is not necessary because the potential exposure of the breastfed infant to iodine is small. However, a lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk for 10 hours (approximately 5 elimination half-lives) after OMNIPAQUE administration to minimize drug exposure to a breastfed infant.

8.4 Pediatric Use

Intrathecal Use

The safety and effectiveness of OMNIPAQUE have been established in pediatric patients aged 2 weeks and older for myelography and CT myelography (lumbar, thoracic, cervical, total columnar) and for CT cisternography. Use of OMNIPAQUE is supported by controlled clinical studies in adults for myelography, in addition to clinical studies in pediatric patients undergoing myelography.

The safety and effectiveness of OMNIPAQUE have not been established for intrathecal use in pediatric patients less than 2 weeks of age.

The safety and effectiveness of OMNIPAQUE for CT cerebral ventriculography have not been established in pediatric patients.

Intra-arterial or Intravenous Use

Cardiac Ventriculography, Aortography, and Pulmonary Angiography

The safety and effectiveness of OMNIPAQUE have been established in pediatric patients from birth to 17 years of age for cardiac ventriculography, aortography, and pulmonary angiography. Use of OMNIPAQUE is supported by controlled clinical studies in adults for cardiac ventriculography and aortography, in addition to controlled clinical studies in pediatric patients undergoing cardiac ventriculography, including aortography.

Excretory Urography

The safety and effectiveness of OMNIPQUE have been established in pediatric patients from birth to 17 years of age for excretory urography. Use of OMNIPAQUE is supported

by controlled clinical studies in adults for urography, in addition to controlled clinical studies in pediatric patients undergoing urography and clinical safety data in pediatric patients down to birth.

CT of the Head and Body

The safety and effectiveness of OMNIPAQUE have been established in pediatric patients from birth to 17 years of age for CT imaging of the head and body. Use of OMNIPAQUE is supported by controlled clinical studies in adults for head and body CT, in addition to clinical studies in pediatric patients undergoing head CT and in 69 pediatric patients undergoing CT of the abdomen after oral administration of diluted OMNIPAQUE plus intravenous administration of OMNIPAQUE.

Selective Coronary Arteriography, Cerebral and Peripheral Arteriography, Intra-arterial Digital Subtraction Angiography, Peripheral Venography, and Intravenous Digital Subtraction Angiography

The safety and effectiveness of OMNIPAQUE have not been established in pediatric patients for selective coronary arteriography, cerebral or peripheral arteriography, intra-arterial digital subtraction angiography, peripheral venography, and intravenous digital subtraction angiography.

Oral or Rectal Use

Examination of the GI Tract

The safety and effectiveness of OMNIPAQUE have been established in pediatric patients, from birth to 17 years of age for examination of the GI tract. Use of OMNIPAQUE is supported by controlled studies in adults for examination of the GI tract, in addition to clinical studies in pediatric patients undergoing examination of the GI tract.

CT of the Abdomen and Pelvis in Conjunction with Intravenous Use

The safety and effectiveness of OMNIPAQUE for CT of the abdomen and pelvis have been established in pediatric patients from birth to 17 years of age. Use is supported by clinical trials in adults, in addition to clinical studies in 69 pediatric patients undergoing CT of the abdomen.

Intraarticular Use

The safety and effectiveness of OMNIPAQUE have not been established in pediatric patients for arthrography.

Body Cavity Use

Voiding Cystourethrography

OMNIPAQUE is indicated for use in pediatric patients from birth to 17 years of age for voiding cystourethrography (VCU). Use for voiding cystourethrography is supported by clinical studies in 51 pediatric patients undergoing VCU.

ERCP, Herniography, and Hysterosalpingography

The safety and effectiveness of OMNIPAQUE have not been established in pediatric patients for ERCP, herniography, or hysterosalpingography.

In general, the frequency of adverse reactions in pediatric patients was similar to that seen in adults *[see Adverse Reactions (6.1)]*. Pediatric patients at higher risk of

experiencing adverse events during contrast-medium administration may include those having asthma, a sensitivity to medication and/or allergens, congestive heart failure, a serum creatinine greater than 1.5 mg/dL or those less than 12 months of age.

Thyroid function tests indicative of thyroid dysfunction, characterized by hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration in pediatric patients, including term and preterm neonates. Some patients were treated for hypothyroidism. After exposure to iodinated contrast media, individualize thyroid function monitoring in pediatric patients 0 to 3 years of age based on underlying risk factors, especially in term and preterm neonates *[see Warnings and Precautions (5.9) and Adverse Reactions (6.2)]*.

8.5 Geriatric Use

In clinical studies of OMNIPAQUE for CT of the head and body, 52 (17%) of patients were 70 and over. No overall differences in safety were observed between these patients and younger patients. Other reported clinical experience has not identified differences in safety and effectiveness between the elderly and younger patients.

Iohexol is substantially excreted by the kidney, and the risk of adverse reactions to iohexol may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

8.6 Renal Impairment

The clearance of iohexol decreases with increasing degree of renal impairment and results in delayed opacification of the urinary system. In addition, preexisting renal impairment increases the risk for acute kidney injury *[see Warnings and Precautions (5.4)]*. Iohexol can be removed by dialysis.

10 OVERDOSAGE

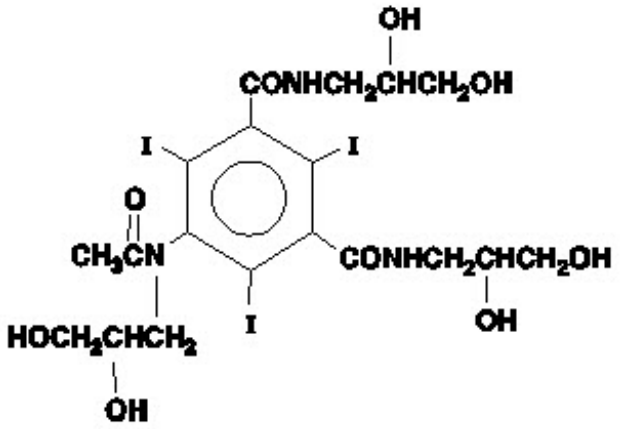
The adverse effects of overdosage in intra-arterial or intravenous administration are life-threatening and affect mainly the pulmonary and cardiovascular systems. The symptoms include: cyanosis, bradycardia, acidosis, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatment of an overdosage is directed toward the support of all vital functions, and prompt institution of symptomatic therapy. Iohexol can be dialyzed.

11 DESCRIPTION

Iohexol is a nonionic radiographic contrast agent available as:

- OMNIPAQUE (iohexol) injection for intrathecal, intra-arterial, intravenous, oral, rectal, intraarticular, and body cavity use
- OMNIPAQUE (iohexol) oral solution for oral use

The chemical name of iohexol is Bis(2,3-dihydroxypropyl)-5-[*N*-(2,3-dihydroxypropyl)-acetamido]-2,4,6- triiodoisophthalamide with a molecular weight of 821.14 (iodine content 46.36%). Iohexol has the following structural formula:



OMNIPAQUE injection is a sterile, pyrogen-free, colorless to pale yellow solution available in five concentrations of iodine:

- OMNIPAQUE 140 mg iodine/mL: Each mL contains 302 mg iohexol (providing 140 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.
- OMNIPAQUE 180 mg iodine/mL: Each mL contains 388 mg iohexol (providing 180 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.
- OMNIPAQUE 240 mg iodine/mL: Each mL contains 518 mg iohexol (providing 240 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.
- OMNIPAQUE 300 mg iodine/mL: Each mL contains 647 mg iohexol (providing 300 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.
- OMNIPAQUE 350 mg iodine/mL: Each mL contains 755 mg iohexol (providing 350 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.

OMNIPAQUE oral solution is a sterile, pyrogen-free, colorless to pale yellow solution available in two concentrations of iodine:

- OMNIPAQUE oral solution 9 mg iodine/mL: Each mL contains 19 mg iohexol (providing 9 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.
- OMNIPAQUE oral solution 12 mg iodine/mL: Each mL contains 26 mg iohexol (providing 12 mg organically bound iodine) and the following inactive ingredients: 0.1 mg edetate calcium disodium and 1.21 mg tromethamine.

The pH is adjusted between 6.8 and 7.7 with hydrochloric acid or sodium hydroxide. OMNIPAQUE injection and OMNIPAQUE oral solution contain no preservatives and no ingredient made from a gluten-containing grain (wheat, barley, or rye).

OMNIPAQUE injection and OMNIPAQUE oral solution have the following physical properties:

Table 21. Physicochemical Properties of OMNIPAQUE

Dosage	Concentration (mg	Osmolality* (mOsmol/kg	Absolute Viscosity	Specific Gravity

Form	(mg iodine/mL)	(mOsmol/kg water)	(cP)		Gravity
			20°C	37°C	37°C
Injection	140	322	2.3	1.5	1.164
	180	408	3.1	2.0	1.209
	240	520	5.8	3.4	1.280
	300	672	11.8	6.3	1.349
	350	844	20.4	10.4	1.406
Oral solution	9	38	1.1	0.8	1.011
	12	45	1.1	0.8	1.014

* *By vapor-pressure osmometry.*

OMNIPAQUE injection has osmolalities from approximately 1.1 to 3 times that of plasma (285 mOsmol/kg water) or cerebrospinal fluid (301 mOsmol/kg water) as shown in the above table and are hypertonic.

OMNIPAQUE oral solution is hypotonic.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The iodine atoms in iohexol provide attenuation of X-rays in direct proportion to the concentration of iohexol. Since concentration changes over time, iohexol provides time-dependent image contrast which may assist in visualizing body structures.

12.2 Pharmacodynamics

Intrathecal Administration

The initial concentration and volume of the contrast medium, in conjunction with patient manipulation and the volume of cerebrospinal fluid (CSF) into which the contrast medium is placed, will determine the extent of the contrast that can be achieved. Following intrathecal injection in conventional radiography, OMNIPAQUE 180 mg iodine/mL, 240 mg iodine/mL, and 300 mg iodine/mL will continue to provide contrast for at least 30 minutes. Slow diffusion of iohexol takes place throughout the CSF with subsequent absorption into the bloodstream. At approximately 1 hour following injection, contrast will no longer be sufficient for conventional myelography.

After administration into the lumbar subarachnoid space, computerized tomography shows the presence of contrast medium in the thoracic region in about 1 hour, in the cervical region in about 2 hours, and in the basal cisterns in 3 to 4 hours.

Intravenous or Intra-arterial Administration

Following intravenous or intra-arterial administration of OMNIPAQUE, the degree of contrast enhancement is directly related to the iodine concentration of an administered dose; peak iodine blood concentrations occur immediately (15 seconds to 120 seconds) following rapid intravenous injection. The time to maximum contrast enhancement can vary, depending on the organ, from the time that peak blood iodine concentrations are reached to one hour after intravenous bolus administration. When a delay between peak blood iodine concentrations and peak contrast is present, it suggests that radiographic

contrast enhancement is at least in part dependent on the accumulation of iodine containing agent within the lesion and outside the blood pool.

Oral Administration

Orally administered OMNIPAQUE produces visualization of the gastrointestinal tract. 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.

Intraarticular Administration

Visualization of the joint spaces can be accomplished by direct injection of contrast medium. For intraarticular cavities, the injected iohexol is absorbed into the surrounding tissue and subsequently absorbed into systemic circulation.

Body Cavity Administration

For most body cavities, the injected iohexol is absorbed into the surrounding tissue and subsequently absorbed into systemic circulation. Examinations of the uterus (hysterosalpingography) and bladder (voiding cystourethrography) involve the almost immediate drainage of contrast medium from the cavity upon conclusion of the radiographic procedure.

12.3 Pharmacokinetics

Following the intravenous administration of iohexol (between 500 mg iodine/kg to 1,500 mg iodine/kg) to 16 adult subjects, apparent first-order terminal elimination half-life was 12.6 hours and total body clearance was 131 (98 to 165) mL/min. Clearance was not dose dependent.

Absorption

As evidenced by the amount recovered in urine, <1% of orally administered iohexol is absorbed from the normal gastrointestinal tract. This amount may increase in the presence of bowel perforation or bowel obstruction.

Distribution

In 16 adult subjects (receiving between 500 mg iodine/kg to 1,500 mg iodine/kg intravenous iohexol) the plasma volume of distribution was165 (108 to 219) mL/kg.

In five adult patients receiving 16 mL to 18 mL of OMNIPAQUE (180 mg iodine/mL) by lumbar intrathecal injection the plasma volume of distribution was 559 (350 to 849) mL/kg.

Elimination

Metabolism

No significant metabolism, deiodination or biotransformation occurs.

Excretion

Following intravenous, intra-arterial or intrathecal administration, iohexol is excreted unchanged by glomerular filtration. Approximately 90% of the intravenously injected iohexol dose is excreted within the first 24 hours. Following intravenous or intraarterial administration, peak urine concentration occurs in the first hour after injection.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed with iohexol to evaluate carcinogenic potential. Iohexol was not genotoxic in a series of studies, including the Ames test, the mouse lymphoma TK locus forward mutation assay, and a mouse micronucleus assay. Iohexol did not impair the fertility of male or female rats when repeatedly administered at intravenous dosages up to 4 g iodine/kg.

14 CLINICAL STUDIES

The safety and effectiveness of OMNIPAQUE for CT of the head were evaluated in three clinical studies. Each study also used an ionic high-osmolar iodinated contrast agent as a comparator. A total of 280 patients were randomized to administration of either OMNIPAQUE (n=142) or the comparator (n=138). OMNIPAQUE patients had a mean age of 52 years (range 16 to 85), 41% were women, and were administered a mean of 692 mg iodine/kg (range 337 to 1,250 mg iodine/kg) by intravenous injection with OMNIPAQUE 240 mg iodine/mL (1 study) or 300 mg iodine/mL (2 studies).

Efficacy was determined from investigator ratings of quality of contrast enhancement (none, poor, good, or excellent; only scans rated as good or excellent were considered diagnostic).

The percentage of OMNIPAQUE-enhanced scans rated as good or excellent was 100% in the two studies using OMNIPAQUE 300 mg iodine/mL, and 79% in the third study using OMNIPAQUE 240 mg iodine/mL.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

OMNIPAQUE (iohexol) injection and OMNIPAQUE (iohexol) oral solution are colorless to pale yellow solutions available in the following presentations:

Dosage Form	Concentration (mg iodine/mL)	Package Size	Package Type & Material	Sale Unit	NDC
	140	50 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1401-52
	180	10 mL	Single-Dose Glass Vials	Boxes of 10	0407-1411-10
	240	10 mL	Single-Dose Glass Vials	Boxes of 10	0407-1412-10
		20 mL	Single-Dose Glass Vials	Boxes of 10	0407-1412-20
		50 mL	Single-Dose Polymer	Boxes of 10	0407-1412-30

			Bottles	10	1412-30
		100 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1412-33
Injection	300	10 mL	Single-Dose Glass Vials	Boxes of 10	0407-1413-10
		30 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1413-59
		50 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1413-61
		100 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1413-63
		125 mL	Single-Dose Glass Bottles	Boxes of 10	0407-1413-53
		150 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1413-65
		500 mL*	Imaging or Pharmacy Bulk Package Polymer Bottles	Boxes of 10	0407-1413-72
	350	50 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1414-89
		75 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1414-90
		100 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1414-91
		125 mL	Single-Dose Glass Bottles	Boxes of 10	0407-1414-76
		150 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1414-93
		200 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1414-94
		500 mL*	Imaging or Pharmacy Bulk	Boxes of	0407-

		500 mL	Package Polymer Bottles	10	1414-72
Oral Solution	9	500 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1415-09
	12	500 mL	Single-Dose Polymer Bottles	Boxes of 10	0407-1416-12

* OMNIPAQUE injection 300 mg iodine/mL and OMNIPAQUE injection 350 mg iodine/mL in bottles of 500 mL can be used as either an Imaging Bulk Package or a Pharmacy Bulk Package *[see Dosage and Administration (2.10, 2.11)]*.

The container closure system components (bottle, vial, stopper, and cap) of OMNIPAQUE injection and OMNIPAQUE oral solution are not made with natural rubber latex.

Storage and Handling

- OMNIPAQUE Injection: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. May be stored in a contrast media warmer for up to one month, not to exceed 37°C (98.6°F).
- OMNIPAQUE Oral Solution: Store between 0°C and 30°C (32°F to 86°F).

Protect from light. Do not freeze. Discard any product that is inadvertently frozen, as freezing may compromise the closure integrity of the immediate container.

17 PATIENT COUNSELING INFORMATION

Hypersensitivity Reactions

Advise the patient concerning the risk of hypersensitivity reactions that can occur both during and after OMNIPAQUE administration. Advise the patient to report any signs or symptoms of hypersensitivity reactions during the procedure and to seek immediate medical attention for any signs or symptoms experienced after discharge *[see Warnings and Precautions (5.3)].*

Advise patients to inform their physician if they develop a rash after receiving OMNIPAQUE *[see Warnings and Precautions (5.12)].*

Acute Kidney Injury

Advise the patient concerning appropriate hydration to decrease the risk of contrast-induced acute kidney injury *[see Warnings and Precautions (5.4)]*.

Extravasation

If extravasation occurs during injection, advise patients to seek medical care for progression of symptoms *[see Warnings and Precautions (5.7)].*

Lactation

Advise a lactating woman that interruption of breastfeeding is not necessary. However, to avoid any exposure, a lactating woman may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration *[see Use in Specific Populations*

(8.2)].

Thyroid Dysfunction

Advise parents/caregivers about the risk of developing thyroid dysfunction after OMNIPAQUE administration. Advise parents/caregivers about when to seek medical care for their child to monitor for thyroid function *[see Warnings and Precautions (5.9)].*

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PRINCIPAL DISPLAY PANEL - 300 mg Bottle Box Label

GE Healthcare

Y-538I

Contains
10 x 500 mL
Bottles

NDC 0407-1413-72

OMNIPAQUE™
(iohexol) Injection

300 mg Iodine/mL

This container can be used either as:

IMAGING BULK PACKAGE
For Intravenous Use Only

or

PHARMACY BULK PACKAGE
Not for Direct Infusion
For Intrathecal, Intra-arterial,
Intravenous, Oral, Rectal,
Intraarticular, or Body Cavity Use

Rx ONLY
See prescribing information for dosage and administration.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. May be stored in a contrast media warmer for up to one month, not to exceed 37°C (98.6°F). Protect from light. Do not freeze. Discard unused OMNIPAQUE 8 hours after initial puncture.

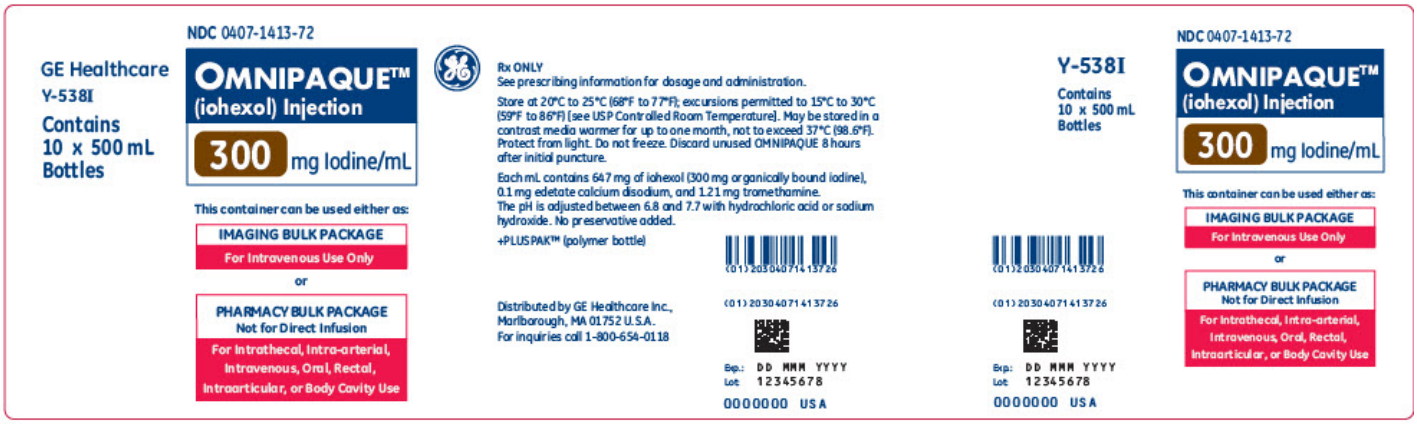
Each mL contains 647 mg of iohexol (300 mg organically bound iodine), 0.1 mg edetate calcium disodium, and 1.21 mg tromethamine.
The pH is adjusted between 6.8 and 7.7 with hydrochloric acid or sodium hydroxide. No preservative added.

+PLUSPAK™ (polymer bottle)

Distributed by GE Healthcare Inc.,
Marlborough, MA 01752 U.S.A.
For inquiries call 1-800-654-0118

Exp.: DD MMM YYYY
Lot: 12345678

0000000 USA



PRINCIPAL DISPLAY PANEL - 350 mg Bottle Box Label

GE Healthcare

Y-548I

Contains
10 x 500 mL
Bottles

NDC 0407-1414-72

OMNIPAQUE™
(iohexol) Injection

350 mg Iodine/mL

This container can be used either as:

IMAGING BULK PACKAGE
For Intravenous Use Only

or

PHARMACY BULK PACKAGE
Not for Direct Infusion

For Intra-arterial,
Intravenous, Oral,
Intraarticular, or Body Cavity Use

NOT FOR INTRATHECAL USE

Rx ONLY
See prescribing information for dosage and administration.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. May be stored in a contrast media warmer for up to one month, not to exceed 37°C (98.6°F). Protect from light. Do not freeze. Discard unused OMNIPAQUE 8 hours after initial puncture.

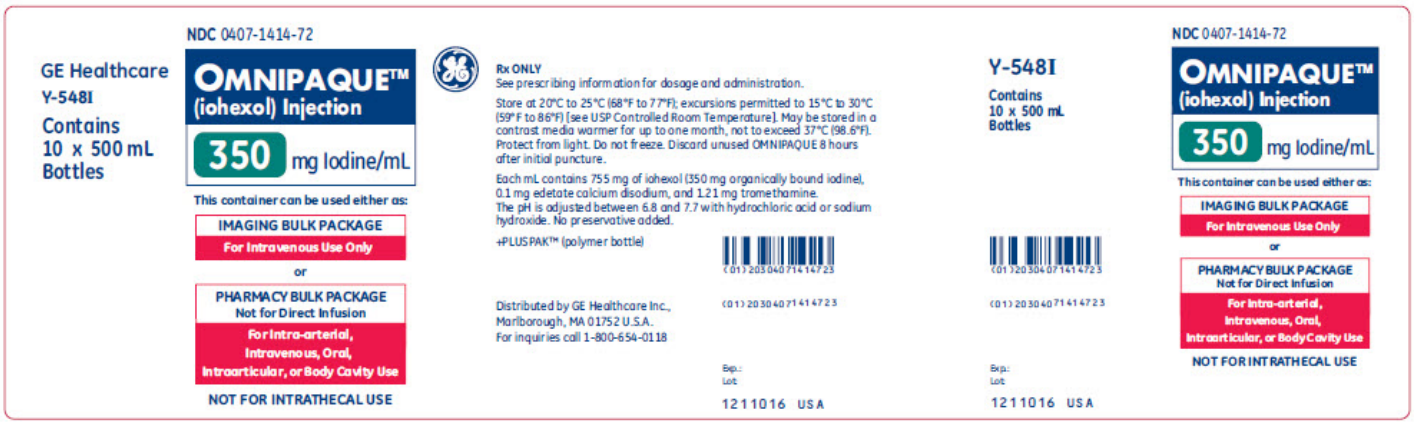
Each mL contains 755 mg of iohexol (350 mg organically bound iodine), 0.1 mg edetate calcium disodium, and 1.21 mg tromethamine.
The pH is adjusted between 6.8 and 7.7 with hydrochloric acid or sodium hydroxide. No preservative added.

+PLUSPAK™ (polymer bottle)

Distributed by GE Healthcare Inc.,
Marlborough, MA 01752 U.S.A.
For inquiries call 1-800-654-0118

Exp.:
Lot:

1211016 USA



OMNIPAQUE

iohexol injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1413
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	Iodine	300 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
tromethamine (UNII: 023C2WHX2V)	1.21 mg in 1 mL
edetate calcium disodium (UNII: 25IH6R4SGF)	0.1 mg in 1 mL
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Product Characteristics			
Color	YELLOW (colorless to pale yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0407-1413-72	10 in 1 BOX	12/21/2016	
1		500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA020608	12/21/2016	

OMNIPAQUE

iohexol injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1414
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	Iodine	350 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
tromethamine (UNII: 023C2WHX2V)	1.21 mg in 1 mL
edetate calcium disodium (UNII: 25IH6R4SGF)	0.1 mg in 1 mL

hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Product Characteristics			
Color	YELLOW (colorless to pale yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0407-1414-72	10 in 1 BOX	12/21/2016	
1		500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020608	12/21/2016	

Labeler - GE Healthcare (053046579)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Ireland Limited		988006565	MANUFACTURE(0407-1413, 0407-1414)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Lindesnes		518890970	API MANUFACTURE(0407-1413, 0407-1414)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Shanghai Co., Ltd.		545292716	MANUFACTURE(0407-1413, 0407-1414)