

## 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, intravascular, oral, rectal, intraarticular, or body cavity use.

OMNIPAQUE (iohexol) oral solution

Initial U.S. Approval: 1985

### WARNING: RISKS WITH INADVERTENT INTRATHECAL ADMINISTRATION OF

OMNIPAQUE injection 140 and 350 mg iodine/mL.  
See full prescribing information for complete boxed warning.  
Inadvertent intrathecal administration may cause death, convulsions/seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema (4, 5.1).

### RECENT MAJOR CHANGES

Warnings and Precautions (5.2) 3/2018  
Contraindications (4) 3/2018

### INDICATIONS AND USAGE

OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen (1).

### DOSAGE AND ADMINISTRATION

The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. See full prescribing information for complete dosing information (2).

### DOSAGE FORMS AND STRENGTHS

#### OMNIPAQUE Injection

- 140 mg of iodine per mL (302 mg of iohexol/mL) in +PlusPak™ (polymer bottle)
- 180 mg of iodine per mL (388 mg of iohexol/mL) in glass vials
- 240 mg of iodine per mL (518 mg of iohexol/mL), 300 mg of iodine per mL (647 mg of iohexol/mL) AND 350 mg of iodine per mL (755 mg of iohexol/mL) in glass vials and bottles and +PlusPak™ (polymer bottle)

#### OMNIPAQUE Oral Solution

- 9 mg of iodine per mL (19mg of iohexol/mL) and 12 mg of iodine per mL (26 mg of iohexol/mL) in +PlusPak™ (polymer bottle)

### CONTRAINDICATIONS

- OMNIPAQUE 140 AND OMNIPAQUE 350 injection are contraindicated for Intrathecal use (4)
- OMNIPAQUE oral solution 9 and 12 are contraindicated for parenteral use (4)

### WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: Life-threatening or fatal reactions can occur. Always have emergency equipment and trained personnel available. (5.3)
- Contrast Induced Acute Kidney Injury: Acute injury including renal failure can occur. Minimize dose and maintain adequate hydration to minimize risk. (5.4)
- Cardiovascular Reactions: Hemodynamic disturbances including shock and cardiac arrest may occur during or after administration. (5.5)

### ADVERSE REACTIONS

Most common adverse reactions (incidence  $\geq$  1.0%) in adult patients after OMNIPAQUE administration. (6.1).

- Intrathecal: Headaches, Pain including backache, neckache, stiffness and neuralgia, nausea, vomiting and dizziness 2.
- Intravascular: 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 and heat sensation

Post-marketing adverse reactions (6.2): Hypersensitivity and manifestations like rash, pruritus, urticarial, and dyspnea, in addition chest pain, and swelling.

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](http://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: 4/2018

## FULL PRESCRIBING INFORMATION: CONTENTS\*

### WARNING: NOT FOR INTRATHECAL USE

#### 1 INDICATIONS AND USAGE

#### 2 DOSAGE AND ADMINISTRATION

- Important Dosage and Administration Instructions
- Intrathecal Dosage and Administration
- Intravascular Dosage and Administration
- Oral or Rectal Dosage and Administration
- Oral Dosage and Administration in Conjunction with Intravenous Administration
- Intraarticular Dosage and Administration
- Body Cavity Dosage and Administration

#### 3 DOSAGE FORMS AND STRENGTHS

#### 4 CONTRAINDICATIONS

#### 5 WARNINGS AND PRECAUTIONS

- Risks Associated with Inadvertent Intrathecal Administration
- Risks with Associated with Inadvertent Parenteral Administration
- Hypersensitivity Reactions
- Contrast Induced Acute Kidney Injury
- Cardiovascular Adverse Reactions
- Thromboembolic Events
- Extravasation and Injection Site Reactions
- Thyroid Storm in Patients with Hyperthyroidism
- Hypertensive Crisis in Patients with Pheochromocytoma
- Sickle Cell Crisis in Patients with Sickle Cell Disease
- Severe Cutaneous Adverse Reactions

#### 6 ADVERSE REACTIONS

- Clinical Trials Experience
- Post-marketing Experience

#### 7 DRUG INTERACTIONS

- Drug-Drug Interactions
- Drug-Laboratory Test Interactions

#### 8 USE IN SPECIFIC POPULATIONS

- Pregnancy
- Lactation
- Pediatric Use
- Geriatric Use

#### 10 OVERDOSAGE

#### 11 DESCRIPTION

- Chemical Characteristics
- Physical Characteristics

#### 12 CLINICAL PHARMACOLOGY

- Mechanism of Action
- Pharmacodynamics
- Pharmacokinetics

#### 13 NONCLINICAL TOXICOLOGY

- Carcinogenesis, Mutagenesis, Impairment of Fertility

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

- How Supplied
- Storage

#### 17 PATIENT COUNSELING INFORMATION

\*sections or subsections omitted from the full prescribing information are not listed

## FULL PRESCRIBING INFORMATION

### WARNING: RISKS WITH INADVERTENT INTRATHECAL ADMINISTRATION

OMNIPAQUE injection, 140 and 350 mg iodine/mL.

*See full prescribing information for complete boxed warning.*

Inadvertent intrathecal administration may cause death, convulsions/seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema ([4](#), [5.1](#))

## 1 INDICATIONS AND USAGE

### 1.1 Intrathecal Administration

#### Adults

OMNIPAQUE 180, 240, and 300

- Myelography (lumbar, thoracic, cervical, total columnar)
- Computerized Tomography [CT] (myelography, cisternography, ventriculography)

#### Pediatrics

OMNIPAQUE 180

- Myelography (lumbar, thoracic, cervical, total columnar)
- CT (myelography, cisternography)

### 1.2 Intravascular Administration

#### Adults

OMNIPAQUE 140

- Intra-arterial digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels.

OMNIPAQUE 240

- CT head imaging
- Peripheral venography (phlebography)

OMNIPAQUE 300

- Aortography including studies of the aortic arch, abdominal aorta and its branches
- CT head and body imaging
- Cerebral arteriography
- Peripheral venography (phlebography)
- Excretory urography

OMNIPAQUE 350

- Angiocardiography (ventriculography, selective coronary arteriography)
- Aortography including studies of the aortic root, aortic arch, ascending aorta, abdominal aorta and its branches
- CT head and body imaging
- Intravenous digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels
- Peripheral arteriography
- Excretory urography

#### Pediatrics

OMNIPAQUE 240

- CT head and body imaging

OMNIPAQUE 300

- Angiocardiography (ventriculography)
- Excretory urography
- CT head and body imaging

OMNIPAQUE 350

- Angiocardiography (ventriculography, pulmonary arteriography, venography, and studies of the collateral arteries)
- Aortography including the aortic root, aortic arch, ascending and descending aorta

### 1.3 Oral or Rectal Administration

#### Adults

OMNIPAQUE 350

- Oral radiographic examination of the gastrointestinal tract

#### Pediatrics

OMNIPAQUE 180, 240 and 300

- Oral and rectal radiographic examination of the gastrointestinal tract

### **1.4 Oral Administration in Conjunction with Intravenous Administration**

#### *Diluted OMNIPAQUE Injection*

##### Adults

OMNIPAQUE 240, 300 and 350 diluted and administered orally in conjunction with OMNIPAQUE 300 administered intravenously.

- CT of the abdomen

##### Pediatrics

OMNIPAQUE 240, 300 and 350 diluted and administered orally in conjunction with OMNIPAQUE 240 or OMNIPAQUE 300 administered intravenously.

- CT of the abdomen

#### *OMNIPAQUE Oral Solution*

##### Adults

OMNIPAQUE oral solution 9 and 12 administered orally in conjunction with OMNIPAQUE 300 administered intravenously.

- CT of the abdomen

##### Pediatrics

OMNIPAQUE oral solution 9 and 12 administered orally in conjunction with OMNIPAQUE 240 or OMNIPAQUE 300 administered intravenously.

- CT of the abdomen

### **1.5. Intraarticular Administration**

##### Adults

OMNIPAQUE 240, 300, and 350

- Arthrography

### **1.6 Body Cavity Administration**

##### Adults

OMNIPAQUE 240

- Endoscopic retrograde pancreatography (ERP) and cholangiopancreatography (ERCP)
- Herniography
- Hysterosalpingography

OMNIPAQUE 300

- Hysterosalpingography

##### Pediatrics

OMNIPAQUE 240, 300 and 350 diluted

- Voiding cystourethrography (VCU)

## **2 DOSAGE AND ADMINISTRATION**

### **2.1 Important Dosage and Administration Instructions**

1. OMNIPAQUE 140, 180, 240, 300 and 350 are indicated for intravascular, oral, rectal, intraarticular, and body cavity administration. OMNIPAQUE 180, 240, and 300 are indicated for intrathecal administration [[see Boxed Warning, Contraindications \(4\), Warnings and Precautions \(5.1\)](#)].
2. Use sterile technique for all handling and administration of OMNIPAQUE for intravascular, intrathecal, intraarticular, and body cavity administration
3. OMNIPAQUE oral solution 9 and 12 are indicated for oral use only [[see Contraindications \(4\) and Warnings and Precautions \(5.2\)](#)].
4. Do not use if tamper-evident ring is broken or missing.
5. OMNIPAQUE injection may be administered at either body (37°C) or room temperature.
6. Inspect OMNIPAQUE injection for particulate matter or discoloration before administration, whenever solution and container permit. Do not administer if OMNIPAQUE injection contains particulate matter or is discolored.
7. Do not mix OMNIPAQUE injection with, or inject in intravenous lines containing, other drugs or total nutritional admixtures.
8. Use the lowest dose necessary to obtain adequate visualization.

9. Individualize the volume, strength, and rate of administration of OMNIPAQUE injection. 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.
10. Avoid extravasation when administering OMNIPAQUE injection intravascularly, especially in patients with severe arterial or venous disease [[see Warnings and Precautions \(5.6\)](#)].
11. Hydrate patients before and after intravascular administration of OMNIPAQUE injection [[see Warnings and Precautions \(5.4\)](#)].
12. Each bottle of OMNIPAQUE injection and oral solution is intended for one procedure only. Discard any unused portion.

## 2.2 Intrathecal Dosage and Administration

- Rate of injection: Injection should be made slowly over 1 to 2 minutes
- Repeat procedures: If sequential or repeat examinations are required, a suitable interval of time between administrations should be observed to allow for normal clearance of the drug from the body; at least 48 hours should be allowed before repeat examination; however, whenever possible, 5 to 7 days is recommended.
- If computerized tomographic (CT) myelography follows myelography, delay imaging several hours to allow the degree of contrast to decrease.

<b>TABLE 1 - INTRATHECAL ADULTS</b>			
*Adults - The usual recommended total doses for use in lumbar, thoracic, cervical, and total columnar myelography in adults are 1,200 mg iodine to 3,100 mg iodine (see table below).			
STUDY TYPE	INJECTION TYPE	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
LUMBAR MYELOGRAPHY	LUMBAR	OMNIPAQUE 180 OMNIPAQUE 240	10 to 17 7 to 12.5
THORACIC MYELOGRAPHY	LUMBAR CERVICAL	OMNIPAQUE 240 OMNIPAQUE 300	6 to 12.5 6 to 10
CERVICAL MYELOGRAPHY	LUMBAR	OMNIPAQUE 240 OMNIPAQUE 300	6 to 12.5 6 to 10
CERVICAL MYELOGRAPHY	C1-2	OMNIPAQUE 180 OMNIPAQUE 240 OMNIPAQUE 300	7 to 10 6 to 12.5 4 to 10
TOTAL COLUMNAR MYELOGRAPHY	LUMBAR	OMNIPAQUE 240 OMNIPAQUE 300	6 to 12.5 6 to 10
* A total dose of 3,100 mg iodine or a concentration of 300 mg iodine/mL should not be exceeded in adults.			

<b>TABLE 2 – INTRATHECAL PEDIATRICS</b>				
*Pediatrics - The usual recommended total doses for lumbar, thoracic, cervical, and/or total columnar myelography by lumbar puncture in children are 360 mg iodine to 2700 mg iodine (see table below). Actual volumes administered depend largely on patient age and the following guidelines are recommended.				
Age	STUDY TYPE	INJECTION TYPE	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
0 up to 3 mos.	LUMBAR, THORACIC, CERVICAL AND/OR	LUMBAR PUNCTURE	OMNIPAQUE 180	2 to 4

3 up to 36 mos.	TOTAL COLUMNAR MYELOGRAPHY	OMNIPAQUE 180	4 to 8
3 up to 7 yrs.		OMNIPAQUE 180	5 to 10
7 up to 13 yrs.		OMNIPAQUE 180	5 to 12
13 to 18 yrs.		OMNIPAQUE 180	6 to 15
*A total dose of 2,700 mg iodine or a concentration of 180 mg iodine/mL should not be exceeded in a single myelographic examination in pediatrics.			

### 2.3 Intravascular Dosage and Administration

#### Intra-arterial Procedures

<b>TABLE 3 ANGIOCARDIOGRAPHIC PROCEDURES</b>		
PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 350	<p><u>VENTRICULOGRAPHY</u> The recommended single dose is 40 mL (Range of 30 mL to 60 mL)</p> <ul style="list-style-type: none"> <li>May be combined with selective coronary arteriography</li> </ul> <p><u>SELECTIVE CORONARY ARTERIOGRAPHY</u> The recommended single dose is 5 mL (Range of 3 mL to 14 mL)</p> <p>Doses may be repeated as necessary Maximum volume with multiple injections should not exceed 250 mL</p>
Pediatrics	OMNIPAQUE 300	<p><u>VENTRICULOGRAPHY</u> The recommended single dose is 1.75 mL/kg (Range of 1.5 mL/kg to 2 mL/kg)</p> <ul style="list-style-type: none"> <li>May be repeated as necessary</li> </ul> <p>Maximum dose with multiple injections should not exceed 6 mL/kg up to a total volume of 291 mL.</p>
	OMNIPAQUE 350	<p><u>VENTRICULOGRAPHY</u> Recommended single dose is 1.25 mL/kg (Range of 1 mL/kg to 1.5 mL/kg).</p> <ul style="list-style-type: none"> <li>May be repeated as necessary</li> </ul> <p>Maximum dose with multiple injections should not exceed 5 mL/kg up to a total volume of 250 mL.</p> <p><u>PULMONARY ANGIOGRAPHY (PULMONARY ARTERIOGRAPHY AND/OR PULMONARY VENOGRAPHY)</u> The recommended single dose is 1 mL/kg.</p>

<b>TABLE 4 AORTOGRAPHY</b>		
PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 300 and 350	<p><u>AORTOGRAPHY AND SELECTIVE VISCERAL ARTERIOGRAPHY</u></p> <p>The recommended single dose is:</p> <ul style="list-style-type: none"> <li>50 mL to 80 mL for the aorta (aortic arch, ascending aorta)</li> </ul>

		<ul style="list-style-type: none"> <li>• 30 mL to 60 mL for abdominal aorta and its branches (celiac, mesenteric, hepatic and splenic arteries)</li> <li>• 5 mL to 15 mL for renal arteries</li> </ul> <p>Injections may be repeated if indicated, but the total volume should not exceed:</p> <ul style="list-style-type: none"> <li>• 290 mL of OMNIPAQUE 300</li> <li>• 250 mL of OMNIPAQUE 350</li> </ul>
	OMNIPAQUE 350	<p><b><u>AORTIC ROOT AND ARCH STUDY WHEN USED ALONE</u></b></p> <p>The recommended single dose is 50 mL (Range of 20 mL to 75 mL)</p>
Pediatrics	OMNIPAQUE 350	<p><b><u>AORTOGRAPHY (AORTIC ROOT, AORTIC ARCH, AND DESCENDING AORTA)</u></b></p> <p>The recommended single dose is 1 mL/kg.</p> <ul style="list-style-type: none"> <li>• May be repeated as necessary</li> </ul> <p>Maximum dose should not exceed 5 mL/kg up to a total volume of 250 mL.</p>

**TABLE 5  
CEREBRAL ARTERIOGRAPHY**

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 300	<p>Single dose for cerebral arteriography is as follows:</p> <ul style="list-style-type: none"> <li>• Common carotid artery (6 mL to 12 mL)</li> <li>• Internal carotid artery (8 mL to 10 mL)</li> <li>• External carotid artery (6 mL to 9 mL)</li> <li>• Vertebral artery (6 mL to 10 mL)</li> </ul>

**TABLE 6  
INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY**

**HEAD, NECK ABDOMINAL, RENAL AND PERIPHERAL VESSELS**

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)		
		ARTERIES	VOLUME/INJECTION (mL)	RATE OF INJECTION (mL/sec)
Adults	OMNIPAQUE 140	Aorta	20 to 45	8 to 20
		Carotid	5 to 10	3 to 6
		Femoral	9 to 20	3 to 6
		Vertebral	4 to 10	2 to 8
		Renal	6 to 12	3 to 6
		Other branches of aorta (includes subclavian, axillary, innominate and iliac)	8 to 25	3 to 10

*Mechanical or hand injection can be used to administer one or more bolus intra-arterial injections of OMNIPAQUE 140.*

<b>TABLE 7 PERIPHERAL ARTERIOGRAPHY</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 300 and 350	The recommended dose for use in peripheral angiography is as follows:  Aortofemoral runoffs: 30 mL to 90 mL of OMNIPAQUE 300 20 mL to 70 mL of OMNIPAQUE 350  Selective arteriograms: 10 mL to 60 mL of OMNIPAQUE 300 10 mL to 30 mL of OMNIPAQUE 350

Intravenous Procedures

<b>TABLE 8 PERIPHERAL VENOGRAPHY (PHLEBOGRAPHY)</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 240 and 300	The recommended dose (per leg) is: 20 mL to 150 mL of OMNIPAQUE 240 40 mL to 100 mL of OMNIPAQUE 300

<b>TABLE 9 EXCRETORY UROGRAPHY</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 300 and 350	The recommended dose is: 0.6 mL/kg to 1.2 mL/kg body weight
Pediatrics	OMNIPAQUE 300	Dose of 0.5 mL/kg to 3 mL/kg of body weight: <ul style="list-style-type: none"> <li>The usual dose for children is 1 mL/kg to 1.5 mL/kg.</li> <li>The total administered dose should not exceed 3 mL/kg.</li> </ul>

<b>TABLE 10 DIGITAL SUBTRACTION ANGIOGRAPHY VESSELS OF THE HEAD, NECK AND ABDOMINAL, RENAL AND PERIPHERAL VESSELS</b>			
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>	<b>RATE OF INJECTION (mL/sec)</b>
Adults	OMNIPAQUE 350	The usual dose for the intravenous digital technique is 30 mL to 50 mL.  Frequently three or more doses may be required, up to a total volume not to exceed 250 mL	7.5 mL/second to 30 mL/second using a pressure injector

TABLE 11 CT SCANNING OF THE HEAD AND BODY		
PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 240, 300 and 350	<p><u>Head and body imaging by rapid injection</u></p> <p><b>CT Imaging – Head:</b></p> <ul style="list-style-type: none"> <li>70 mL to 150 mL of OMNIPAQUE 300</li> <li>80 mL of OMNIPAQUE 350</li> </ul> <p><b>CT Imaging – Body:</b></p> <ul style="list-style-type: none"> <li>50 mL to 200 mL of OMNIPAQUE 300</li> <li>60 mL to 100 mL of OMNIPAQUE 350</li> </ul> <p><u>Head imaging by infusion</u></p> <p><b>CT Imaging – Head:</b></p> <ul style="list-style-type: none"> <li>120 mL to 250 mL of OMNIPAQUE 240</li> </ul>
Pediatrics	OMNIPAQUE 240 and 300	<p><b>CT Imaging – Head and Body:</b></p> <p>1 mL/kg to 2 mL/kg (with maximum = 3 mL/kg)</p> <p>maximum single dose = 116 mL</p>

## 2.4 Oral or Rectal Dosage and Administration

Oral and Rectal Administration – Undiluted OMNIPAQUE Injection for Radiographic Examination of the Gastrointestinal (GI) Tract

TABLE 12 DOSING FOR RADIOGRAPHIC EXAMINATION OF THE GI TRACT			
PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	ORAL VOLUME (mL)	RECTAL VOLUME* (mL)
Adults	OMNIPAQUE 350	The recommended dose is 50 mL to 100 mL	-
Pediatrics	OMNIPAQUE 180, 240 and 300	The recommended dose is 5 mL to 100 mL.	The recommended dose is 5 mL to 100 mL*
Less than 3 months old	OMNIPAQUE 180	5 mL to 30 mL	-*
Three months to 3 years	OMNIPAQUE 180, 240 and 300	Up to 60 mL	-*
Four years to 10 years	OMNIPAQUE 180, 240 and 300	Up to 80 mL	-*
Greater than 10 years		Up to 100 mL	-*

\*When given rectally, larger volumes may be used

## 2.5 Oral Dosage and Administration in Conjunction with Intravenous Administration

- See Table 16 for concurrent intravenous dosing

Oral Administration of Diluted OMNIPAQUE Injection in Conjunction with Intravenous Administration of OMNIPAQUE Injection for CT of the Abdomen

<b>TABLE 13 DOSING OF DILUTED** OMNIPAQUE INJECTION FOR ORAL ADMINISTRATION</b>			
<b>PATIENT POPULATION</b>	<b>ORAL CONCENTRATION (mg iodine/mL)</b>	<b>ORAL VOLUME (mL)</b>	<b>ADMINISTRATION INSTRUCTIONS</b>
Adults	OMNIPAQUE 240, 300 and 350 DILUTED TO 6 to 12 mg iodine/mL  (See below Table 14)	Recommended oral dose is:  • 500 mL to 1000 mL.	Smaller administered volumes can be given if the iodine concentration in final diluted product is increased (see below Table 14)  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.
Pediatrics	OMNIPAQUE 240, 300 and 350 DILUTED TO 9 to 21 mg iodine/mL  (See below Table 14)	Recommended oral dose is:  • 180 mL to 750 mL.  Do not exceed an oral dose of 5 grams iodine for patients less than 3 years old.  Do not exceed an oral dose of 10 grams iodine for patients 3 to 18 years old.	Smaller administered volumes can be given if the iodine concentration in final diluted product is increased (see below Table 14)  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.
**Dilutions of OMNIPAQUE should be prepared just prior to use and any unused portion discarded after the procedure.			

<b>TABLE 14 PROCEDURE FOR PREPARATION OF DILUTED OMNIPAQUE INJECTION FOR ORAL ADMINISTRATION</b>						
OMNIPAQUE to be mixed with liquid such as water, carbonated beverage, milk, infant formula, or juice to achieve one liter of oral contrast agent.						
Final iodine Concentration of Diluted Contrast Agent	OMNIPAQUE 240		OMNIPAQUE 300		OMNIPAQUE 350	
	Volume of Contrast Agent (mL)	Volume of Liquid (mL)	Volume of Contrast Agent (mL)	Volume of Liquid (mL)	Volume of Contrast Agent (mL)	Volume of Liquid (mL)
6	25	975	20	980	17	983
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

Oral Administration of OMNIPAQUE Oral Solution in Conjunction with Intravenous Administration of OMNIPAQUE Injection for CT of the Abdomen

<b>TABLE 15 DOSING AND ADMINISTRATION OF OMNIPAQUE ORAL SOLUTION</b>			
<b>PATIENT POPULATION</b>	<b>ORAL CONCENTRATION (mg iodine/mL)</b>	<b>ORAL VOLUME (mL)</b>	<b>ADMINISTRATION INSTRUCTIONS</b>
Adults	OMNIPAQUE oral solution 9 and 12	The recommended oral dose is: <ul style="list-style-type: none"> <li>• 500 mL to 1000 mL</li> </ul>	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.
Pediatrics	OMNIPAQUE oral solution 9 and 12	The recommended oral dose is: <ul style="list-style-type: none"> <li>• 180 mL to 750 mL</li> </ul> Do not exceed an oral dose of 5 grams iodine for patients less than 3 years old.  Do not exceed an oral dose of 10 grams iodine for patients 3 to 18 years old.	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.

<b>TABLE 16 INTRAVENOUS ADMINISTRATION OF OMNIPAQUE INJECTION FOR CT OF THE ABDOMEN IN CONJUNCTION WITH ORALLY ADMINISTERED DILUTED OMNIPAQUE INJECTION OR OMNIPAQUE ORAL SOLUTION</b>			
<b>PATIENT POPULATION</b>	<b>INTRAVENOUS CONCENTRATION (mg iodine/mL)</b>	<b>INTRAVENOUS VOLUME (mL)</b>	<b>ADMINISTRATION INSTRUCTIONS</b>
Adults	OMNIPAQUE 300	The recommended dose is: <ul style="list-style-type: none"> <li>• 100 to 150 mL</li> </ul>	Administer up to 40 minutes AFTER consumption of the oral dose
Pediatrics	OMNIPAQUE 240 and 300	The recommended dose is: <ul style="list-style-type: none"> <li>• 2 mL/kg with a range of 1 mL/kg to 2 mL/kg (maximum 3 mL/kg)</li> </ul>	Administer up to 60 minutes AFTER consumption of the oral dose

## 2.6 Intraarticular Dosage and Administration

<b>TABLE 17 ARTHROGRAPHY</b>				
<b>PATIENT POPULATION</b>	<b>LOCATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>	<b>DOUBLE CONTRAST/SINGLE CONTRAST</b>
Adults	*Knee	OMNIPAQUE 240	5 mL to 15 mL	Lower volumes recommended for double-contrast examinations; higher volumes recommended for single-contrast examinations.
		OMNIPAQUE 300	5 mL to 15 mL	
		OMNIPAQUE 350	5 mL to 10 mL	
Adults	*Shoulder	OMNIPAQUE 240	3 mL	
		OMNIPAQUE 300	10 mL	
Adults	*Temporomandibular	OMNIPAQUE 300	0.5 mL to 1 mL	

\*Passive or active manipulation is used to disperse the medium throughout the joint space.

## 2.7 Body Cavity Dosage and Administration

### Body Cavity Administration - Undiluted OMNIPAQUE Injection

<b>TABLE 18 ENDOSCOPIC RETROGRADE PANCREATOGRAPHY (ERP) ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ECRP)</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 240	10 mL to 50 mL but may vary depending on individual anatomy and/or disease state.

<b>TABLE 19 HYSTEROSALPINGOGRAPHY</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 240 and 300	15 mL to 20 mL but may vary depending on individual anatomy and/or disease state.

<b>TABLE 20 HERNIOGRAPHY</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>
Adults	OMNIPAQUE 240	50 mL but may vary depending on individual anatomy and/or disease state.

### Body Cavity Administration - Diluted OMNIPAQUE Injection

<b>TABLE 21 VOIDING CYSTOURETHROGRAPHY (VCU) (CAN BE PERFORMED IN CONJUNCTION WITH EXCRETORY UROGRAPHY)</b>		
<b>PATIENT POPULATION</b>	<b>CONCENTRATION (mg iodine/mL)</b>	<b>VOLUME (mL)</b>

Pediatrics	<p>The concentration may vary depending upon the patient's size and age and with the technique and equipment used.</p> <p>OMNIPAQUE injection may be diluted with Sterile Water for Injection.</p> <p><i>See below Table 22.</i></p>	<p>OMNIPAQUE injection may be diluted, utilizing aseptic technique, with Sterile Water for Injection to a concentration of 50 mg iodine/mL to 100 mg iodine/mL for voiding cystourethrography.</p> <p>Range:</p> <ul style="list-style-type: none"> <li>• 50 mL to 300 mL of OMNIPAQUE at a concentration of 100 mg iodine/mL</li> <li>• 50 mL to 600 mL of OMNIPAQUE at a concentration of 50 mg iodine/mL.</li> </ul>
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**TABLE 22  
PROCEDURE FOR PREPARATION OF DILUTED OMNIPAQUE INJECTION FOR VCU**

Final iodine Concentration of Diluted Contrast Agent (mg iodine/mL)	Volume of OMNIPAQUE 240 (mL)	Volume of Sterile Water for Injection (mL)	Volume of OMNIPAQUE 300 (mL)	Volume of Sterile Water for Injection (mL)	Volume of OMNIPAQUE 350 (mL)	Volume of Sterile Water for Injection (mL)
100	100	140	100	200	100	250
90		167		233		289
80		200		275		338
70		243		330		400
60		300		400		483
50		380		500		600

*Dilutions of OMNIPAQUE should be prepared just prior to use and any unused portion discarded after the procedure.*

### 3 DOSAGE FORMS AND STRENGTHS

#### OMNIPAQUE (iohexol) Injection and Oral Solution

Sterile, pyrogen-free, gluten-free, colorless to pale yellow solution containing the nonionic, water-soluble x-ray contrast medium iohexol, and available in the following strengths and formats:

#### OMNIPAQUE (iohexol) Injection

- 140 mg of organically bound iodine per mL (302 mg iohexol/mL)
  - Available in +PLUSPAK™ (polymer bottle)
- 180 mg of organically bound iodine per mL (388 mg iohexol/mL)
  - Available in glass vials
- 240 mg of organically bound iodine per mL (518 mg iohexol/mL)
- 300 mg of organically bound iodine per mL (647 mg iohexol/mL)
- 350 mg of organically bound iodine per mL (755 mg iohexol/mL)
  - Available in glass vials and bottles and +PLUSPAK™ (polymer bottle)

#### OMNIPAQUE Oral Solution

- 9 mg of organically bound iodine per mL (19 mg iohexol/mL)
- 12 mg of organically bound iodine per mL (26 mg iohexol/mL)
  - Available in +PLUSPAK™ (polymer bottle)

### 4 CONTRAINDICATIONS

- OMNIPAQUE 140 and OMNIPAQUE 350 are contraindicated for intrathecal use [[see Warnings and Precautions \(5.1\)](#)]:

- OMNIPAQUE oral solution 9 and 12 are contraindicated for parenteral administration [[see Warnings and Precautions \(5.2\)](#)]:

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Risks Associated with Inadvertent Intrathecal Administration

OMNIPAQUE injection 140 and 350 are contraindicated for intrathecal use [[see Contraindications \(4\)](#) and [Dosage and Administration \(2.1\)](#)]. Inadvertent Intrathecal administration 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 Inadvertent Parenteral Administration of Omnipaque Oral Solution

OMNIPAQUE oral solution 9 and 12 are contraindicated for parenteral administration [[see Contraindications \(4\)](#) and [Dosage and Administration \(2.1\)](#)]. Adverse reactions such as hemolysis may occur if administered intravascularly. Do not administer OMNIPAQUE oral solution 9 and 12 parenterally.

### 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 3 minutes), but reactions can occur up to hours later. There is an increased risk in patients with a history of a previous reaction to contrast agent, and known allergies (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 Contrast Induced 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 upon 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

#### Angiocardiology

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiology procedures with both ionic and nonionic contrast media. 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 iodinated contrast agents, which increases the risk of clotting. Avoid angiocardiology in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

### 5.7 Extravasation and Injection Site Reactions

Extravasation of OMNIPAQUE during intravascular injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure intravascular placement of catheters prior to injection. 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 intravascular 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 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 intravascularly 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.

### 5.10 Sickle Cell Crisis in Patients with Sickle Cell Disease.

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

### 5.11 Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). 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.

## 6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Risks Associated with Inadvertent Intrathecal Administration [[see Warnings and Precautions \(5.1\)](#)]
- Risks Associated with Inadvertent Parenteral Administration [[see Warnings and Precautions \(5.2\)](#)]
- Hypersensitivity Reactions [[see Warnings and Precautions \(5.3\)](#)]
- Contrast Induced Kidney Injury [[see Warnings and Precautions \(5.4\)](#)]
- Cardiovascular Adverse Reactions [[see Warnings and Precautions \(5.5\)](#)]
- Thromboembolic Events [[see Warnings and Precautions \(5.7\)](#)]
- Severe Cutaneous Reactions [[see Warnings and Precautions \(5.11\)](#)]

### 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*

TABLE 23 ADVERSE REACTIONS – INTRATHECAL ADMINISTRATION		
In controlled clinical studies involving 1531 patients using OMNIPAQUE the following adverse reactions were reported:		
System Organ Class	Adverse Reaction	Incidence
Nervous System	Headaches	18%
Musculoskeletal and Connective Tissue	Pain including backache, neckache, stiffness and neuralgia	8%
Gastrointestinal System	Nausea	6%
	Vomiting	3%

Nervous System	Dizziness	2%
Other Reactions	Feeling of heaviness, hypotension, hypertonia, sensation of heat, sweating, vertigo, loss of appetite, drowsiness, hypertension, photophobia, tinnitus, neuralgia, paresthesia, difficulty in micturition, and neurological changes	<0.1%

*Pediatric Patients*

<b>TABLE 24 ADVERSE REACTIONS – INTRATHECAL ADMINISTRATION</b>				
In clinical studies involving 152 patients for pediatric myelography by lumbar puncture, adverse events following the use of OMNIPAQUE 180 were generally similar to those reported in adults.				
Procedure	System Organ Class	Adverse Reaction	Incidence	
Myelography by Lumbar Puncture	Nervous System	Headache	9%	
	Gastrointestinal System	Vomiting	6%	
	Musculoskeletal and Connective Tissue	Backache	1.3%	
	Other Reactions  <i>All were transient and mild with no clinical sequelae.</i>	Fever		<0.7%
		Hives		
		Stomachache		
		Visual Hallucination		
Neurological Changes				

Intravascular Administration

Immediately following intravascular injection of contrast medium, a transient sensation of mild warmth is not unusual. Warmth is less frequent with OMNIPAQUE than with ionic contrast media.

*Adults*

In controlled clinical studies involving 1485 patients, the following adverse reactions occurred (Table 25):

<b>TABLE 25 ADVERSE REACTIONS – INTRAVASCULAR ADMINISTRATION</b>		
System Organ Class	Adverse Reaction	Incidence
Cardiovascular System	Arrhythmias including PVCs and PACs (2%),	2%
	Hypotension	0.7%
	Others including cardiac failure, asystole, bradycardia, tachycardia, and vasovagal reaction	≤ 0.3%
Nervous System	Vertigo (including dizziness and lightheadedness)	0.5%
	Pain	3%
	Vision Abnormalities (including blurred vision and photomas)	2%
	Taste Perversion	1%
Other Reactions	Anxiety, fever, motor and speech dysfunction, convulsion, paresthesia, somnolence, stiff neck, hemiparesis, syncope, shivering, transient ischemic attack, cerebral infarction, and nystagmus	Individual incidence of 0.3% or less
Respiratory System	Dyspnea, rhinitis, coughing, and laryngitis	Individual incidence of 0.2% or less
Gastrointestinal System	Nausea	2%
	Vomiting	0.7%

	Others including diarrhea, dyspepsia, cramp, and dry mouth	Individual incidence of less than 0.1%.
Skin and Subcutaneous Tissues	Urticaria	0.3%
	Purpura	0.1%
	Abscess	0.1%
	Pruritus	0.1%

*Pediatric Patients*

In controlled clinical studies involving 391 patients for pediatric angiocardiology, urography, and CT head imaging, adverse reactions following the use of OMNIPAQUE 240, 300, and 350 were generally similar in quality and frequency to adults (Table 26):

<b>TABLE 26 ADVERSE REACTIONS – INTRAVASCULAR ADMINISTRATION</b>		
<b>System Organ Class</b>	<b>Adverse Reaction</b>	<b>Incidence</b>
Cardiovascular System	Ventricular Tachycardia	0.5%
	2:1 Heart Block	0.5%
	Hypertension	0.3%
	Anemia	0.3%
General Disorders and Administration Site Conditions	Pain	0.8%
	Fever	0.5%
Nervous System	Convulsion	0.3%
	Taste Abnormality	0.5%
Respiratory System	Congestion	0.3%
	Apnea	0.3%
Gastrointestinal System	Nausea	1%
	Vomiting	2%
Endocrine System	Hypoglycemia	0.3%
Skin and Subcutaneous Tissue	Rash	0.3%

Oral Administration for Examination of the Gastrointestinal Tract

*Adults*

Nausea, vomiting, and diarrhea have been most frequently reported following orally administered undiluted OMNIPAQUE for radiographic examination of the gastrointestinal tract. In controlled clinical studies involving 54 adult patients for oral radiographic examination of the gastrointestinal tract using undiluted OMNIPAQUE 350 the following adverse reactions were reported (Table 27):

<b>TABLE 27 ADVERSE REACTIONS – ORAL ADMINISTRATION OF UNDILUTED OMNIPAQUE 350</b>		
<b>System Organ Class</b>	<b>Adverse Reaction</b>	<b>Incidence</b>
Gastrointestinal System	Diarrhea	42%
	Nausea	15%
	Vomiting	11%
	Abdominal Pain	7%
	Flatulence	2%
Nervous System	Headache	2%

*Pediatrics Patients (Oral and Rectal Administration):*

In clinical studies involving 58 pediatric patients, the adverse reactions were found to mostly affect the gastrointestinal system with diarrhea (36%), vomiting (9%), nausea (5%) and abdominal pain (2%). However, fever (5%), hypotension (2%) and urticaria (2%) were also reported.

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

### *Adults*

In a controlled clinical study involving 44 adult patients receiving oral administration of diluted OMNIPAQUE (4-9 mg iodine/mL) in conjunction with intravenously injected OMNIPAQUE 300 for CT examination of the abdomen, adverse reactions were limited to a single report of vomiting.

### *Pediatric Patients*

In clinical studies involving 69 pediatric patients receiving oral administration of diluted OMNIPAQUE (9-29 mg iodine/mL) in conjunction with intravenously administered OMNIPAQUE 240 and OMNIPAQUE 300 for CT examination of the abdomen, adverse reactions were limited to a single report of vomiting (1.4%).

## Body Cavity Use

### *Adults*

In controlled clinical studies involving 285 adult patients for various body cavity examinations using OMNIPAQUE 240, 300 and 350, the most frequent adverse reactions were administration site reactions: pain 26% and swelling 22%, were exclusively reported for arthrography and were generally related to the procedure rather than the contrast medium. Patients also experienced heat (7%). All other adverse reaction occurred at a rate less than or equal to 1%.

### *Pediatric Patients*

No 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 additional reactions listed by indication 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 reactions:* Acute kidney injury.

### Intravascular Administration

*Cardiovascular 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.

*Hemodynamic reactions:* 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 reactions:* Acute kidney injury, nephropathy toxic (CIN), transient proteinuria, oliguria or anuria, increased serum creatinine.

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

*Endocrine reactions:* Hyperthyroidism. Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for 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).

## **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<sup>2</sup>; in patients with a history of hepatic impairment, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure, and reinstitute metformin only after renal function is stable.

#### Radioactive Iodine

Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for 6-8 weeks.

#### Beta-adrenergic Blocking Agents

The use of beta-adrenergic blocking agents lowers the threshold for and increases the severity of contrast reactions and reduces the responsiveness of treatment of hypersensitivity reactions with epinephrine. Because of the risk of hypersensitivity reactions, use caution when administering OMNIPAQUE to patients taking beta-blockers.

#### Drugs that Lower Seizure Threshold

Drugs that lower seizure threshold, especially phenothiazine derivatives including those used for their antihistaminic or anti-nauseant properties, are not recommended for use with intrathecal administration of OMNIPAQUE.

## CNS Active Drugs

Drugs such as monoamine oxidase (MAO) inhibitors, tricyclic antidepressants, CNS stimulants, psychoactive drugs described as analeptics, major tranquilizers, or antipsychotic drugs. Such medications should be discontinued at least 48 hours before myelography, should not be used for the control of nausea or vomiting during or after myelography, and should not be resumed for at least 24 hours post procedure. In non-elective procedures in patients on these drugs, consider prophylactic use of anticonvulsants.

## **7.2 Drug Laboratory Test Interactions**

### Effect on Thyroid tests

If iodine-containing isotopes are to be administered for the diagnosis of thyroid disease, the iodine-binding capacity of thyroid tissue may be reduced for up to 2 weeks after contrast medium administration. Thyroid function tests that do not depend on iodine estimation, e.g., T<sub>3</sub> resin uptake or direct thyroxine assays, are not affected.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

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 2-4% and 15-20%, 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 180 have been established in pediatric patients 2 weeks to 17 years of age for myelography (lumbar, thoracic, cervical, total columnar) and for CT (myelography, cisternography). Use of OMNIPAQUE 180 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 180 have not been established for intrathecal use in patient pediatric patients less than 2 weeks of age. The safety and effectiveness of OMNIPAQUE 240 and 300 have not been established in pediatric patients for myelography (lumbar, thoracic, cervical, total columnar) and for CT (myelography, cisternography, or ventriculography).

### Intravascular Use

#### *Angiocardiography (ventriculography, pulmonary arteriography, venography, and studies of the collateral arteries) and aortography*

The safety and effectiveness of OMNIPAQUE 300 have been established in pediatric patients from birth to 17 years of age for angiocardiography (ventriculography) and of OMNIPAQUE 350 in pediatric patients from birth to 17 years of age for angiocardiography (ventriculography, pulmonary arteriography, venography, and studies of the collateral arteries) and aortography. Use of OMNIPAQUE 300 and 350 is supported by controlled clinical studies in adults for angiocardiography and aortography, in addition to controlled clinical studies in pediatric patients undergoing angiocardiography, including aortography. The safety and effectiveness of OMNIPAQUE 300 have not been established in pediatric patients for aortography

#### *Intra-arterial digital subtraction angiography, intravenous digital subtraction angiography, cerebral arteriography, or peripheral arteriography and venography*

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

#### *CT of the Head and Body*

The safety and effectiveness of OMNIPAQUE 240 and 300 have been established in pediatric patients from birth to 17 years of age for CT imaging of the head and body. Use of OMNIPAQUE 240 and 300 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. The safety and effectiveness of OMNIPAQUE 350 have not been established in pediatric patients for CT imaging of the head and body.

#### *Urography*

The safety and effectiveness of OMNIPQUE 300 have been established in pediatric patients from birth to 17 years of age for urography. Use of OMNIPAQUE 300 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.

### Oral or Rectal Use.

#### *Undiluted OMNIPAQUE Injection*

The safety and effectiveness of OMNIPAQUE 180, 240, and 300 administered orally and rectally have been established in pediatric patients, from birth to 17 years of age for examination of the GI tract. Use of OMNIPAQUE 180, 240, and 300 administered orally and rectally 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.

### Oral Use in Conjunction with Intravenous Use

#### *Diluted OMNIPAQUE Injection*

The safety and effectiveness of OMNIPAQUE injection diluted to concentrations from 9 to 21 mg iodine / mL administered orally in conjunction with OMNIPAQUE injection administered intravenously for CT of the abdomen 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 after oral administration of diluted OMNIPAQUE plus intravenous administration of OMNIPAQUE.

### *OMNIPAQUE Oral Solution*

The safety and effectiveness of OMNIPAQUE oral solution 9 and 12 administered orally in conjunction with OMNIPAQUE injection administered intravenously for CT of the abdomen in pediatric patients have been established in pediatric patients from birth to 17 years of age. Use is supported by the data establishing safety and effectiveness for OMNIPAQUE injection diluted and administered orally in conjunction with OMNIPAQUE injection administered intravenously for CT of the abdomen in pediatric patients.

### Intraarticular use

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

### Body Cavity Use

OMNIPAQUE 240, 300, 350 diluted to concentrations from 50 mg iodine/mL to 100 mg iodine/mL is indicated for use in pediatric patients from birth to 17 years of age for voiding cystourethrography (VCU). The use for voiding cystourethrography is supported by clinical studies in 51 pediatric patients undergoing VCU. 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 hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to pediatric patients, including infants. Some patients were treated for hypothyroidism [[see Adverse Reactions \(6.2\)](#)].

## **8.5 Geriatric Use**

In clinical studies of OMNIPAQUE for CT, 52/299 (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 response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. In general, dose selection for an elderly patient should be cautious usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy [[see Intravenous Administration Studies \(14.1\)](#)].

## **10 OVERDOSAGE**

### **10.1 Intravascular Administration**

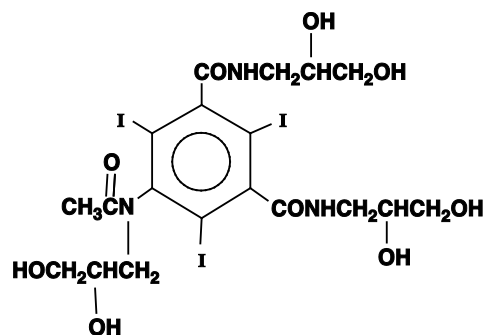
The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular systems. The symptoms included: cyanosis, bradycardia, acidosis, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatment of an overdosage is directed toward the support of all vital functions, and prompt institution of symptomatic therapy. Iohexol displays a low affinity for serum or plasma proteins and is poorly bound to serum albumin and can be dialyzed.

## **11 DESCRIPTION**

### **11.1 Chemical Characteristics**

OMNIPAQUE (iohexol) injection is a nonionic, x-ray or radiographic contrast medium for intrathecal, intravenous, oral and body cavity use. OMNIPAQUE oral solution is for oral use only.

OMNIPAQUE injection and OMNIPAQUE oral solution are both provided as sterile, pyrogen-free and gluten-free solutions. OMNIPAQUE injection and OMNIPAQUE oral solution are colorless to pale yellow solutions. 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 available in five strengths:

- OMNIPAQUE 140 mg iodine/mL (302 mg of iohexol/mL): Each mL contains 140 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium
- OMNIPAQUE 180 mg iodine/mL (388 mg of iohexol/mL): Each mL contains 180 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium
- OMNIPAQUE 240 mg iodine/mL (518 mg of iohexol/mL): Each mL contains 240 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium
- OMNIPAQUE 300 mg iodine/mL (647 mg of iohexol/mL): Each mL contains 300 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium
- OMNIPAQUE 350 mg iodine/mL (755 mg of iohexol/mL): Each mL contains 350 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium

OMNIPAQUE oral solution is available in two strengths:

- OMNIPAQUE oral solution 9 mg iodine/mL (19 mg of iohexol/mL): Each mL contains 9 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium
- OMNIPAQUE oral solution 12 mg iodine/mL (26 mg of iohexol/mL): Each mL contains 12 mg organically bound iodine, 1.21 mg tromethamine and 0.1 mg edetate calcium disodium

The pH is adjusted between 6.8 and 7.7 with hydrochloric acid or sodium hydroxide. OMNIPAQUE injection and OMNIPAQUE oral solution are sterilized by autoclaving and contain no preservatives.

## 11.2 Physical Characteristics

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

Presentation	Concentration (mg iodine/mL)	Osmolality* (mOsmol/kg water)	Absolute Viscosity (cP)		Specific Gravity
			20°C	37°C	
OMNIPAQUE 140	140	322	2.3	1.5	1.164
OMNIPAQUE 180	180	408	3.1	2.0	1.209
OMNIPAQUE 240	240	520	5.8	3.4	1.280
OMNIPAQUE 300	300	672	11.8	6.3	1.349
OMNIPAQUE 350	350	844	20.4	10.4	1.406
OMNIPAQUE oral solution 9	9	38	1.1	0.8	1.011

OMNIPAQUE oral solution 12	12	45	1.1	0.8	1.014
*By vapor-pressure osmometry.					

OMNIPAQUE 140, OMNIPAQUE 180, OMNIPAQUE 240, OMNIPAQUE 300, and OMNIPAQUE 350 have osmolalities from approximately 1.1 to 3.0 times that of plasma (285 mOsmol/kg water) or cerebrospinal fluid (301 mOsmol/kg water) as shown in the above table and are hypertonic under conditions of use.

OMNIPAQUE oral solution 9 and OMNIPAQUE oral solution 12 are hypotonic under conditions of use (see table above).

## 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, 240, and 300 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.

#### Intravascular Administration

Following intravascular 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 1500 mg iodine/kg) to 16 adult human subjects, apparent first-order terminal elimination half-life was 12.6 hrs and total body clearance was 131 (98-165) 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 1500 mg iodine/kg intravenous iohexol) the plasma volume of distribution was 165 (108-219) mL/kg.

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

#### Elimination

##### *Metabolism*

No significant metabolism, deiodination or biotransformation occurs.

##### *Excretion*

Following intravascular 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 intravascular administration, peak urine concentrations 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.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

### 16.1 How Supplied

Volume/Concentration	Configuration	NDC
<b>OMNIPAQUE 140 (140 mg iodine/mL) – Boxes of 10</b>		
50 mL	+PLUSPAK™ (polymer bottle)	0407-1401-52
<b>OMNIPAQUE 180 (180 mg iodine/mL) – Boxes of 10</b>		
10 mL	Glass Vial	0407-1411-10
20 mL	Glass Vial	0407-1411-20
<b>OMNIPAQUE 240 (240 mg iodine/mL) – Boxes of 10</b>		
10 mL	Glass Vial	0407-1412-10
20 mL	Glass Vial	0407-1412-20
50 mL	Glass Vial	0407-1412-50

Volume/Concentration	Configuration	NDC
50 mL	+PLUSPAK™ (polymer bottle)	0407-1412-30
100 mL	Glass Vial	0407-1412-60
100 mL	+PLUSPAK™ (polymer bottle)	0407-1412-33
150 mL	Glass Vial	0407-1412-49
150 mL fill in 200 mL	+PLUSPAK™ (polymer bottle)	0407-1412-34
200 mL	+PLUSPAK™ (polymer bottle)	0407-1412-35
<b>OMNIPAQUE 300 (300 mg iodine/mL) – Boxes of 10</b>		
10 mL	Glass Vial	0407-1413-10
30 mL	Glass Vial	0407-1413-30
30 mL fill in 50 mL	+PLUSPAK™ (polymer bottle)	0407-1413-59
50 mL	Glass Vial	0407-1413-50
50 mL	Glass Bottle	0407-1413-51
50 mL	+PLUSPAK™ (polymer bottle)	0407-1413-61
75 mL fill in 100 mL	+PLUSPAK™ (polymer bottle)	0407-1413-62
100 mL	Glass Bottle	0407-1413-60
100 mL	+PLUSPAK™ (polymer bottle)	0407-1413-63
125 mL fill in 150 mL	Glass Bottle	0407-1413-53
150 mL	Glass Bottle	0407-1413-90
150 mL fill in 200 mL	+PLUSPAK™ (polymer bottle)	0407-1413-65
200 mL	+PLUSPAK™ (polymer bottle)	0407-1413-66
<b>OMNIPAQUE 350 (350 mg iodine/mL) – Boxes of 10</b>		
50 mL	Glass Vial	0407-1414-50
50 mL	Glass Bottle	0407-1414-51
50 mL	+PLUSPAK™ (polymer bottle),	0407-1414-89
75 mL fill in 100 mL	+PLUSPAK™ (polymer bottle)	0407-1414-90
100 mL	Glass Bottle	0407-1414-60
100 mL	+PLUSPAK™ (polymer bottle)	0407-1414-91
125 mL fill in 150 mL	Glass Bottle	0407-1414-76
150 mL	Glass Bottle	0407-1414-03
150 mL fill in 200 mL	+PLUSPAK™ (polymer bottle)	0407-1414-93

Volume/Concentration	Configuration	NDC
200 mL fill in 250 mL	Glass Bottle	0407-1414-04
200 mL	+PLUSPAK™ (polymer bottle)	0407-1414-94
250 mL	Glass Bottle	0407-1414-80
<b>OMNIPAQUE Oral Solution 9 (9 mg iodine/mL) – Boxes of 10</b>		
500 mL	+PLUSPAK™ (polymer bottle)	0407-1415-09
<b>OMNIPAQUE Oral Solution 12 (12 mg iodine/mL) – Boxes of 10</b>		
500 mL	+PLUSPAK™ (polymer bottle)	0407-1415-12

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

## 16.2 Storage

Protect OMNIPAQUE glass vials and bottles and +PLUSPAK™ polymer bottles from light. Do not freeze. Discard any product that is inadvertently frozen, as freezing may compromise the closure integrity of the immediate container.

### OMNIPAQUE Injection 140, 180, 240, 300 and 350

Store at controlled room temperature, 20°- 25°C (68° - 77°F); excursions permitted to 15°- 30°C (59°- 86°F) [see USP Controlled Room Temperature]. May be stored in a contrast media warmer for up to one month at 36-38°C (96.8 - 98.6°F).

### OMNIPAQUE Oral Solution 9 and 12

Store between 0° and 30°C (32°- 86°F).

## 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 \(5.11\)](#)].

### Contrast Induced 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 \(8.2\)](#)].

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