OMNIPAQUE- iohexol injection, solution
OMNIPAQUE- iohexol solution
GE Healthcare Inc.

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, Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age (5.9)	4/2023

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. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information (2).

DOSAGE FORMS AND STRENGTHS

OMNIPAQUE Injection (3)

- 140 mg of iodine per mL (302 mg of iohexol/mL) in +*Plus*Pak™ polymer bottles
- 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 +*Plus*Pak™ polymer bottles

OMNIPAQUE Oral Solution (3)

- 9 mg of iodine per mL (19 mg of iohexol/mL) and 12 mg of iodine per mL (26 mg of iohexol/mL) in +*Plus*Pak™ polymer bottles

CONTRAINDICATIONS

- OMNIPAQUE injection 140 and 350 are contraindicated for intrathecal use (4)
- OMNIPAQUE oral solution 9 and 12 are contraindicated for parenteral use (4)
- OMNIPAQUE body cavity 240 and 300 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. (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 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 ≥ 1.0%) in adult patients after OMNIPAQUE administration. (6.1)

- Intrathecal: Headaches, Pain including backache, neckache, stiffness and neuralgia, nausea, vomiting and dizziness
- 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, urticaria, 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.

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: 4/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* 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

Inadvertent intrathecal administration may cause death, convulsions/seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema *[see Contraindications (4) and Warnings and Precautions (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)
- Peripheral arteriography
- 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
- 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), and Warnings and Precautions (5.1)].*
- Use sterile technique for all handling and administration of OMNIPAQUE for intravascular, intrathecal, intraarticular, and body cavity administration.
- OMNIPAQUE oral solution 9 and 12 are indicated for oral use only *[see* Contraindications (4) *and Warnings and Precautions (5.2)].*
- Do not use if tamper-evident ring is broken or missing.
- OMNIPAQUE injection may be administered at either body (37°C, 98.6°F) or room temperature (20° to 25°C, 68° to 77°F).
- 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.
- Do not mix OMNIPAQUE injection with, or inject in intravenous lines containing, other drugs or total nutritional admixtures.
- Use the lowest dose necessary to obtain adequate visualization.

- 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.
- Avoid extravasation when administering OMNIPAQUE injection intravascularly, especially in patients with severe arterial or venous disease *[see Warnings and Precautions (5.6)].*
- Hydrate patients before and after intravascular administration of OMNIPAQUE injection *[see Warnings and Precautions (5.4)].*
- 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 days to 7 days is recommended.
- If computerized tomographic (CT) myelography follows myelography, delay imaging several hours to allow the degree of contrast to decrease.

TABLE 1 - INTRATHECAL 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 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.*

TABLE 2 – INTRATHECAL 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 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 TOTAL COLUMNAR MYELOGRAPHY	LUMBAR PUNCTURE	OMNIPAQUE 180	2 to 4
3 up to 36 mos.			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

TABLE 3 ANGIOCARDIOGRAPHIC PROCEDURES

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 350	VENTRICULOGRAPHY • The recommended single dose is 40 mL (Range of 30 mL to 60 mL) • May be combined with selective coronary arteriography SELECTIVE CORONARY ARTERIOGRAPHY • The recommended single dose is 5 mL (Range of 3 mL to 14 mL) Doses may be repeated as necessary. Maximum volume with multiple injections should not exceed 250 mL.
Pediatrics	OMNIPAQUE 300	VENTRICULOGRAPHY The recommended single dose is 1.75 mL/kg (Range of 1.5 mL/kg to 2 mL/kg) • May be repeated as necessary Maximum dose with multiple injections should not exceed 6 mL/kg up to a total volume of 291 mL.
		VENTRICULOGRAPHY Recommended single dose is 1.25 mL/kg (Range of 1 mL/kg to 1.5 mL/kg). • May be repeated as necessary

	OMNIPAQUE 350	Maximum dose with multiple injections should not exceed 5 mL/kg up to a total volume of 250 mL. PULMONARY ANGIOGRAPHY (PULMONARY ARTERIOGRAPHY AND/OR PULMONARY VENOGRAPHY) The recommended single dose is 1 mL/kg.

TABLE 4 AORTOGRAPHY

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 300 and 350	AORTOGRAPHY AND SELECTIVE VISCERAL ARTERIOGRAPHY The recommended single dose is: • 50 mL to 80 mL for the aorta (aortic arch, ascending aorta) • 30 mL to 60 mL for abdominal aorta and its branches (celiac, mesenteric, hepatic and splenic arteries) • 5 mL to 15 mL for renal arteries Injections may be repeated if indicated, but the total volume should not exceed: • 290 mL of OMNIPAQUE 300 • 250 mL of OMNIPAQUE 350
	OMNIPAQUE 350	AORTIC ROOT AND ARCH STUDY WHEN USED ALONE The recommended single dose is 50 mL (Range of 20 mL to 75 mL)
Pediatrics	OMNIPAQUE 350	AORTOGRAPHY (AORTIC ROOT, AORTIC ARCH, AND DESCENDING AORTA) The recommended single dose is 1 mL/kg. • May be repeated as necessary Maximum dose should not exceed 5 mL/kg up to a total volume of 250 mL.

TABLE 5 CEREBRAL ARTERIOGRAPHY

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 300	Single dose for cerebral arteriography is as follows: • 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)

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.

TABLE 7 PERIPHERAL ARTERIOGRAPHY

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
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

TABLE 8 PERIPHERAL VENOGRAPHY (PHLEBOGRAPHY)

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 240	The recommended dose (per leg) is: • 20 mL to 150 mL of OMNIPAQUE 240

Adults	and 300	• 40 mL to 100 mL of OMNIPAQUE 300

TABLE 9 EXCRETORY UROGRAPHY

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 300 and 350	The recommended dose is: • 0.6 mL/kg to 1.2 mL/kg body weight
Pediatrics	OMNIPAQUE 300	Dose ranging from 0.5 mL/kg to 3 mL/kg of body weight: • The usual dose for children is 1 mL/kg to 1.5 mL/kg. • The total administered dose should not exceed 3 mL/kg.

TABLE 10 DIGITAL SUBTRACTION ANGIOGRAPHY HEAD, NECK, ABDOMINAL, RENAL AND PERIPHERAL VESSELS

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)	RATE OF INJECTION (mL/sec)
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	<u>Head and body imaging by rapid injection</u> **CT Imaging – Head:** • 70 mL to 150 mL of OMNIPAQUE 300 • 80 mL of OMNIPAQUE 350 **CT Imaging – Body:** • 50 mL to 200 mL of OMNIPAQUE 300 • 60 mL to 100 mL of OMNIPAQUE 350

		Head imaging by infusion **CT Imaging – Head:** • 120 mL to 250 mL of OMNIPAQUE 240
Pediatrics	OMNIPAQUE 240 and 300	**CT Imaging – Head and Body:** • 1 mL/kg to 2 mL/kg (with maximum = 3 mL/kg) • Maximum single dose = 116 mL

* *OMNIPAQUE may be used with an automated contrast injection system or contrast management system cleared for use with OMNIPAQUE [see Dosage and Administration (2.8)]. See device labeling for device indications, additional information, and instructions for use.*

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

TABLE 13 DOSING OF DILUTED* OMNIPAQUE INJECTION FOR ORAL ADMINISTRATION

PATIENT POPULATION	ORAL CONCENTRATION (mg iodine/mL)	ORAL VOLUME (mL)	ADMINISTRATION INSTRUCTIONS
Adults	OMNIPAQUE 240, 300 and 350 DILUTED to 6 to 12 mg iodine/mL *(See Table 14 below)*	Recommended oral dose is: • 500 mL to 1,000 mL	Smaller administered volumes can be given if the iodine concentration in final diluted product is increased *(See Table 14 below)* 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 Table 14 below)*	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 Table 14 below)* 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*.

TABLE 14 PROCEDURE FOR PREPARATION OF DILUTED OMNIPAQUE INJECTION FOR ORAL ADMINISTRATION

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	**OMNIPAQUE 240**	**OMNIPAQUE 300**	**OMNIPAQUE 350**

Concentration of Diluted Contrast Agent (mg iodine/mL)	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

TABLE 15 DOSING AND ADMINISTRATION OF OMNIPAQUE ORAL SOLUTION

PATIENT POPULATION	ORAL CONCENTRATION (mg iodine/mL)	ORAL VOLUME (mL)	ADMINISTRATION INSTRUCTIONS
Adults	OMNIPAQUE oral solution 9 and 12	The recommended oral dose is: • 500 mL to 1,000 mL	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: • 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.	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.

TABLE 16 INTRAVENOUS ADMINISTRATION OF OMNIPAQUE INJECTION FOR CT OF THE ABDOMEN IN CONJUNCTION WITH ORALLY ADMINISTERED DILUTED OMNIPAQUE INJECTION OR OMNIPAQUE

ORAL SOLUTION

PATIENT POPULATION	INTRAVENOUS CONCENTRATION (mg iodine/mL)	INTRAVENOUS VOLUME* (mL)	ADMINISTRATION INSTRUCTIONS
Adults	OMNIPAQUE 300	The recommended dose is: • 100 mL to 150 mL	Administer up to 40 minutes AFTER consumption of the oral dose
Pediatrics	OMNIPAQUE 240 and 300	The recommended dose is: • 2 mL/kg with a range of 1 mL/kg to 2 mL/kg (maximum 3 mL/kg)	Administer up to 60 minutes AFTER consumption of the oral dose

* *OMNIPAQUE may be used with an automated contrast injection system or contrast management system cleared for use with OMNIPAQUE [see Dosage and Administration (2.8)]. See device labeling for device indications, additional information, and instructions for use.*

2.6 Intraarticular Dosage and Administration

TABLE 17 ARTHROGRAPHY

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

* *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

TABLE 18 ENDOSCOPIC RETROGRADE PANCREATOGRAPHY (ERP) ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ECRP)

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Adults	OMNIPAQUE 240	10 mL to 50 mL but may vary depending on individual anatomy

		and/or disease state.

TABLE 19 HYSTEROSALPINGOGRAPHY

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

TABLE 20 HERNIOGRAPHY

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

Body Cavity Administration - Diluted OMNIPAQUE Injection

TABLE 21 VOIDING CYSTOURETHROGRAPHY (VCU) (CAN BE PERFORMED IN CONJUNCTION WITH EXCRETORY UROGRAPHY)

PATIENT POPULATION	CONCENTRATION (mg iodine/mL)	VOLUME (mL)
Pediatrics	The concentration may vary depending upon the patient's size and age and with the technique and equipment used. OMNIPAQUE injection may be diluted with Sterile Water for Injection. *(See Table 22 below).*	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. Range: • 50 mL to 300 mL of DILUTED OMNIPAQUE at a concentration of 100 mg iodine/mL • 50 mL to 600 mL of DILUTED OMNIPAQUE at a concentration of 50 mg iodine/mL.

TABLE 22 PROCEDURE FOR PREPARATION OF DILUTED* OMNIPAQUE INJECTION FOR VCU

Final Iodine Concentration of Diluted Contrast Agent (mg	Volume of OMNIPAQUE 240 (mL)	Volume of Sterile Water for Injection	Volume of OMNIPAQUE 300 (mL)	Volume of Sterile Water for Injection	Volume of OMNIPAQUE 350 (mL)	Volume of Sterile Water for Injection

iodine/mL)		(mL)		(mL)		(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.*

2.8 Instructions for Use with an Automated Contrast Injection System or Contrast Management System for CT of the Head and Body

- OMNIPAQUE may be used with an automated contrast injection system cleared for use with contrast media.
  - See above Important Dosage and Administration Instructions for OMNIPAQUE (2.1).
  - See device labeling for information on device indications, instructions for use, and techniques to help assure safe use.
- OMNIPAQUE 300 mg iodine/mL and 350 mg iodine/mL in 150 mL bottles may be used with a contrast media management system cleared for use with OMNIPAQUE 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.
  - Use sterile technique for penetrating the container closure of OMNIPAQUE 300 and 350 and transferring OMNIPAQUE solution. The container closure may be penetrated only one time with a suitable sterile component of the contrast media management system cleared for use with OMNIPAQUE 300 and 350 in 150 mL bottles.
  - Once the OMNIPAQUE 300 and 350 Injection 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

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 +*PLUS*PAK™ (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 +*PLUS*PAK™ polymer bottles.

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 +*PLUS*PAK™ polymer bottles.

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)]*
- OMNIPAQUE body cavity 240 and 300 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 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

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

Angiocardiography

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiography 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 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 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 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 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.

5.11 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.

5.12 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 (5.6)*]
- 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

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

TABLE 24 ADVERSE REACTIONS – INTRATHECAL ADMINISTRATION

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 *All were transient and mild with no clinical sequelae.*	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).

TABLE 25 ADVERSE REACTIONS – INTRAVASCULAR ADMINISTRATION

System Organ Class	Adverse Reaction	Incidence
Cardiovascular System	Arrhythmias including PVCs and PACs	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
	Nausea	2%
	Vomiting	0.7%

Gastrointestinal System	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 angiocardiography, urography, and CT head imaging, adverse reactions following the use of OMNIPAQUE 240, 300, and 350 were generally similar in quality and frequency to those reported in adults (Table 26).

TABLE 26 ADVERSE REACTIONS – INTRAVASCULAR ADMINISTRATION

System Organ Class	**Adverse Reaction**	**Incidence**
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).

TABLE 27 ADVERSE REACTIONS – ORAL ADMINISTRATION OF UNDILUTED OMNIPAQUE 350

System Organ Class	**Adverse Reaction**	**Incidence**

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

Arthrography: 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, toxic nephropathy (CIN), transient proteinuria, oliguria or anuria, increased serum creatinine

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

Endocrine Reactions: 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: Pain (49%), somnolence and fever each with an individual incidence of 3%.

Gastrointestinal system: 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

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 to 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 antinauseant 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_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 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 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, 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.

10 OVERDOSAGE

10.1 Intravascular Administration

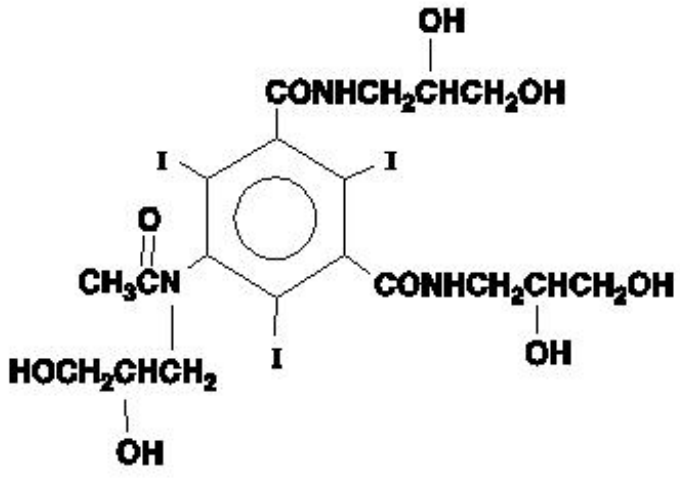
The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular systems. The symptoms included: cyanosis, bradycardia, acidosis, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatment of an overdosage is directed toward the support of all vital 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, rectal 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	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 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 1500 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 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 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Volume/Concentration	Configuration	NDC
OMNIPAQUE 140 (140 mg iodine/mL) – Boxes of 10		
50 mL	+*PLUS*PAK™ (polymer bottle)	0407-1401-52
OMNIPAQUE 180 (180 mg iodine/mL) – Boxes of 10		
10 mL	Glass Vial	0407-1411-10
OMNIPAQUE 240 (240 mg iodine/mL) – Boxes of 10		
10 mL	Glass Vial	0407-1412-10
20 mL	Glass Vial	0407-1412-20
50 mL	+*PLUS*PAK™ (polymer bottle)	0407-1412-30
100 mL	+*PLUS*PAK™ (polymer	0407-1412-33

100 mL	bottle)	0407-1412-53
OMNIPAQUE 300 (300 mg iodine/mL) – Boxes of 10		
10 mL	Glass Vial	0407-1413-10
30 mL fill in 50 mL	+*PLUS*PAK™ (polymer bottle)	0407-1413-59
50 mL	+*PLUS*PAK™ (polymer bottle)	0407-1413-61
100 mL	+*PLUS*PAK™ (polymer bottle)	0407-1413-63
125 mL fill in 150 mL	Glass Bottle	0407-1413-53
150 mL fill in 200 mL	+*PLUS*PAK™ (polymer bottle)	0407-1413-65
OMNIPAQUE 350 (350 mg iodine/mL) – Boxes of 10		
50 mL	+*PLUS*PAK™ (polymer bottle)	0407-1414-89
75 mL fill in 100 mL	+*PLUS*PAK™ (polymer bottle)	0407-1414-90
100 mL	+*PLUS*PAK™ (polymer bottle)	0407-1414-91
125 mL fill in 150 mL	Glass Bottle	0407-1414-76
150 mL fill in 200 mL	+*PLUS*PAK™ (polymer bottle)	0407-1414-93
200 mL	+*PLUS*PAK™ (polymer bottle)	0407-1414-94
OMNIPAQUE Oral Solution 9 (9 mg iodine/mL) – Boxes of 10		
500 mL	+*PLUS*PAK™ (polymer bottle)	0407-1415-09
OMNIPAQUE Oral Solution 12 (12 mg iodine/mL) – Boxes of 10		
500 mL	+*PLUS*PAK™ (polymer bottle)	0407-1416-12

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 and Handling

Protect OMNIPAQUE glass vials and bottles and +*PLUS*PAK™ 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° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. May be stored in a contrast media warmer for up to one month at 36° to 38°C (96.8° to 100.4°F).

OMNIPAQUE Oral Solution 9 and 12

Store between 0° and 30°C (32° to 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 (5.12)].*

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)].

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)].*

Distributed by GE Healthcare Inc., Marlborough, MA 01752 U.S.A.

Product of Norwegian Origin.

PRINCIPAL DISPLAY PANEL - 140 mgI/mL Bottle Label

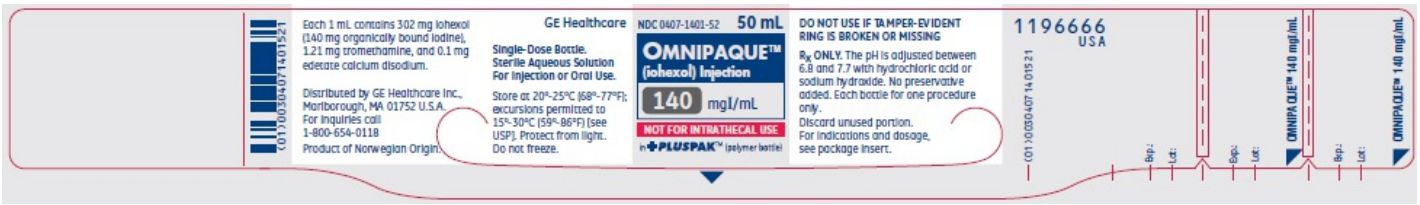
NDC 0407-1401-52
50 mL

OMNIPAQUE™
(iohexol) Injection

140 mgI/mL

NOT FOR INTRATHECAL USE

in +PLUSPAK™ (polymer bottle)



PRINCIPAL DISPLAY PANEL - 180 mgI/mL Vial Label

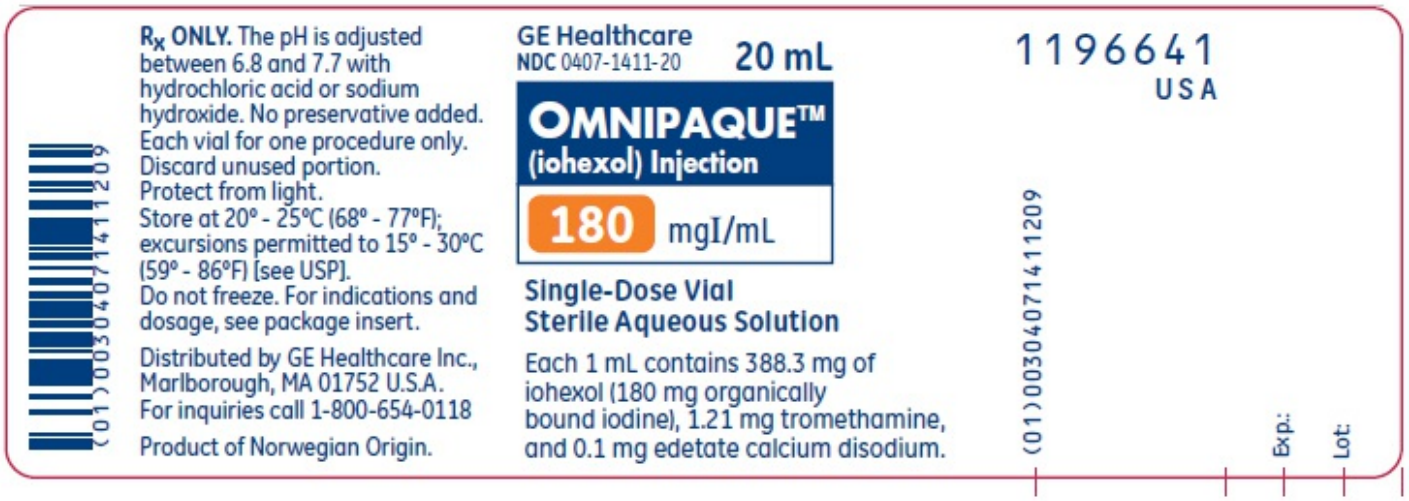
GE Healthcare
NDC 0407-1411-20
20 mL

OMNIPAQUE™
(iohexol) Injection

180 mgI/mL

Single-Dose Vial
Sterile Aqueous Solution

Each 1 mL contains 388.3 mg of iohexol (180 mg organically bound iodine), 1.21 mg tromethamine, and 0.1 mg edetate calcium disodium.



PRINCIPAL DISPLAY PANEL - 240 mgI/mL Bottle Label

NDC 0407-1412-34
150 mL

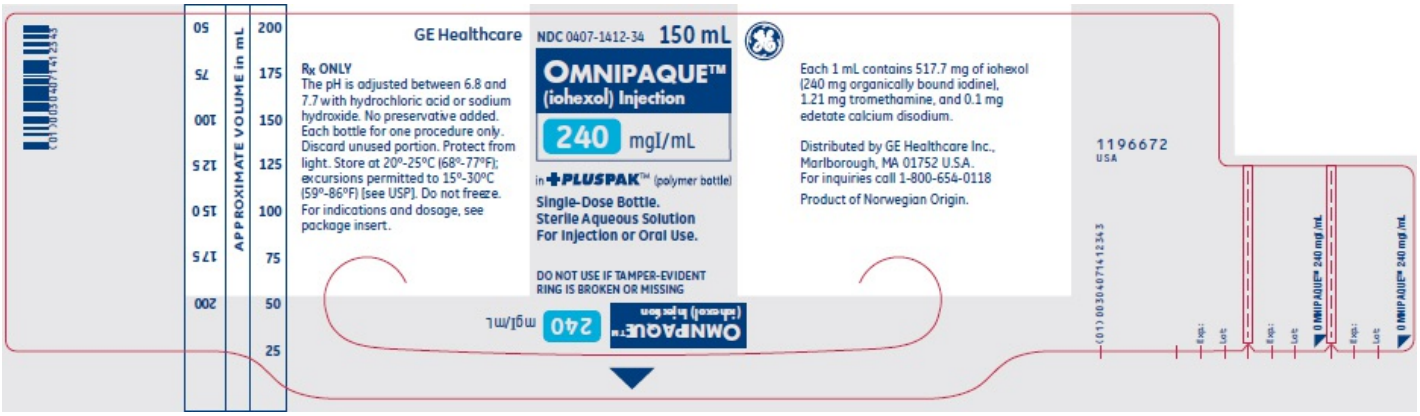
OMNIPAQUE™
(iohexol) Injection

240 mgI/mL

in +PLUSPAK™ (polymer bottle)

Single-Dose Bottle.
Sterile Aqueous Solution
For Injection or Oral Use.

DO NOT USE IF TAMPER-EVIDENT
RING IS BROKEN OR MISSING



PRINCIPAL DISPLAY PANEL - 300 mg Iodine/mL Bottle Label

NDC 0407-1413-65
150 mL

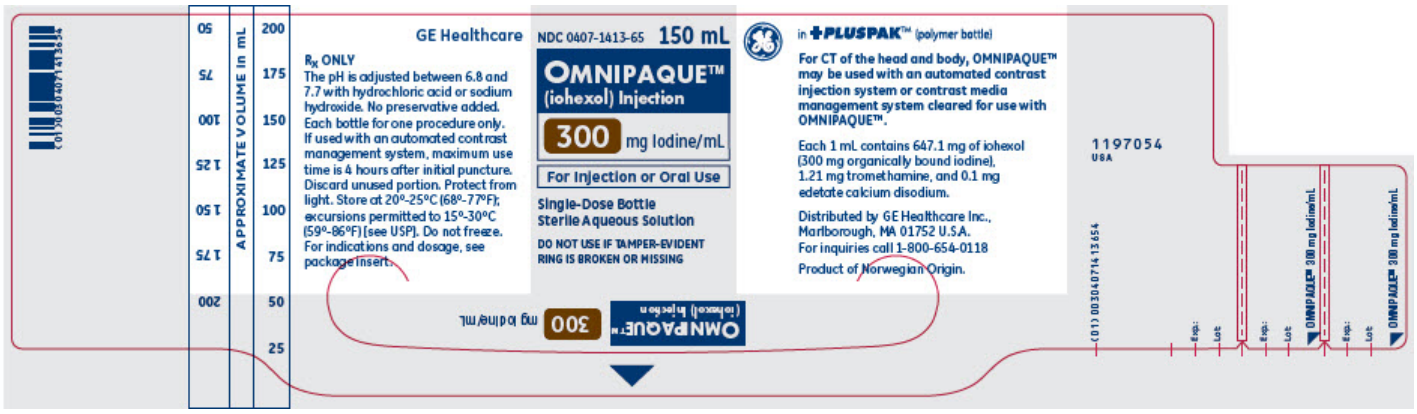
OMNIPAQUE™
(iohexol) Injection

300 mg Iodine/mL

For Injection or Oral Use

Single-Dose Bottle
Sterile Aqueous Solution

DO NOT USE IF TAMPER-EVIDENT
RING IS BROKEN OR MISSING



PRINCIPAL DISPLAY PANEL - 350 mgI/mL Bottle Label

NDC 0407-1414-93
150 mL

OMNIPAQUE™
(iohexol) Injection

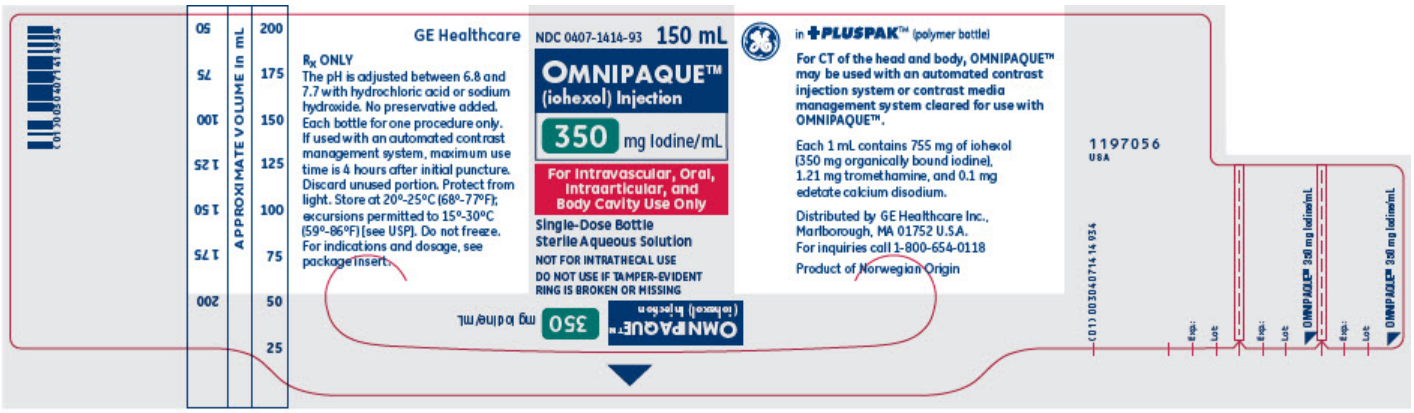
350 mg Iodine/mL

For Intravascular, Oral,
Intraarticular, and
Body Cavity Use Only

Single-Dose Bottle
Sterile Aqueous Solution

NOT FOR INTRATHECAL USE

DO NOT USE IF TAMPER-EVIDENT
RING IS BROKEN OR MISSING



PRINCIPAL DISPLAY PANEL - 9 mg iodine/mL Bottle Label

NDC 0407-1415-09
500 mL

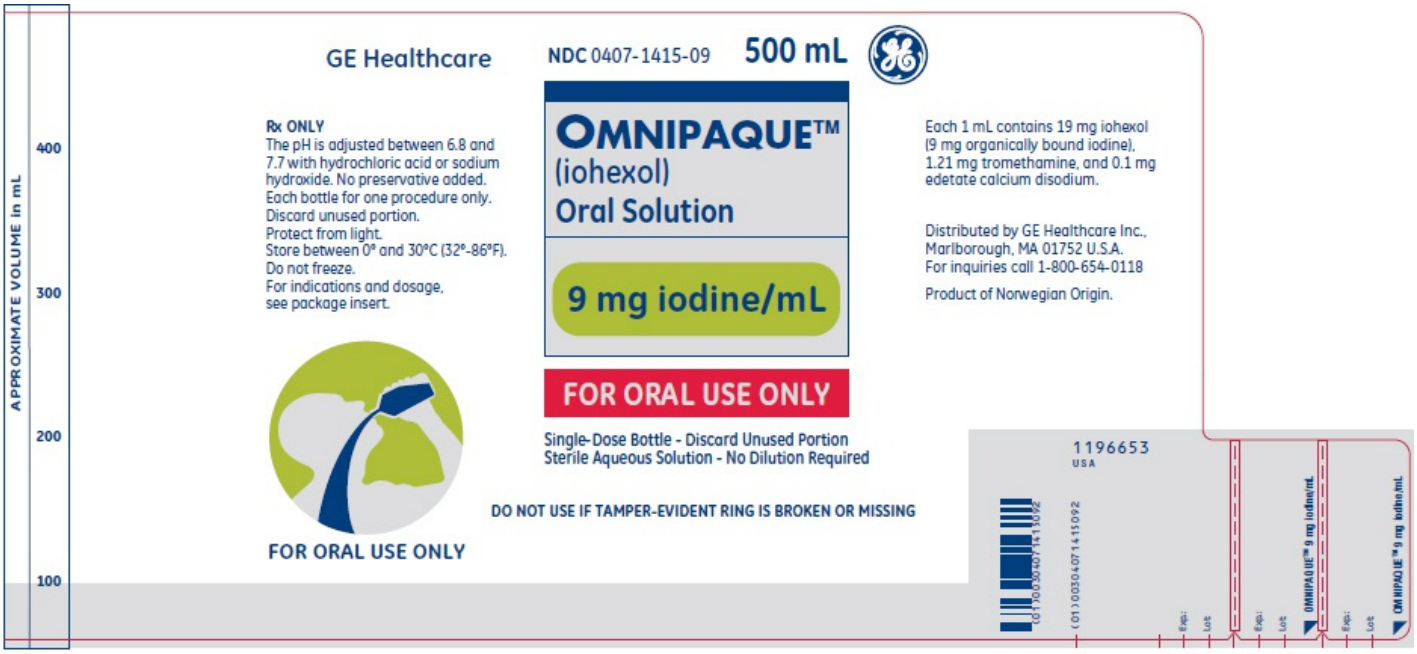
OMNIPAQUE™
(iohexol)
Oral Solution

9 mg iodine/mL

FOR ORAL USE ONLY

Single-Dose Bottle - Discard Unused Portion
Sterile Aqueous Solution - No Dilution Required

DO NOT USE IF TAMPER-EVIDENT RING IS BROKEN OR MISSING



PRINCIPAL DISPLAY PANEL - 12 mg iodine/mL Bottle Label

NDC 0407-1416-12
500 mL

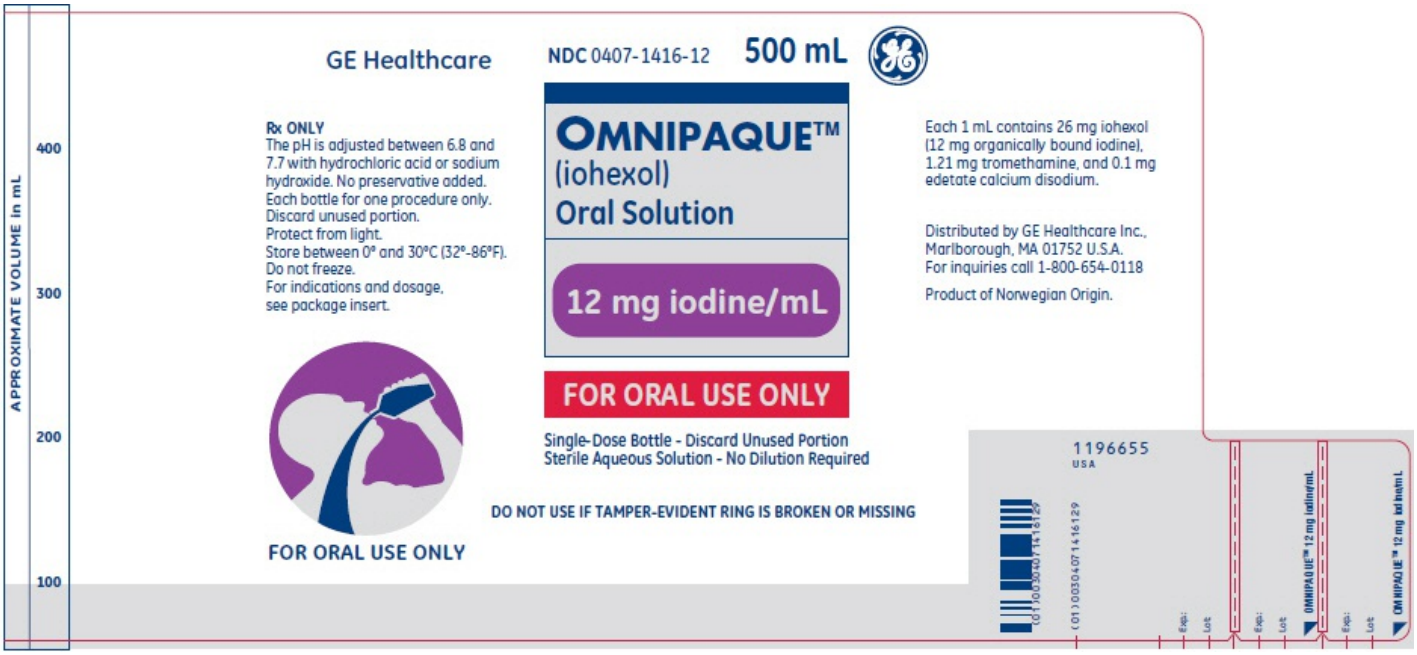
OMNIPAQUE™
(iohexol)
Oral Solution

12 mg iodine/mL

FOR ORAL USE ONLY

Single-Dose Bottle - Discard Unused Portion
Sterile Aqueous Solution - No Dilution Required

DO NOT USE IF TAMPER-EVIDENT RING IS BROKEN OR MISSING



OMNIPAQUE

iohexol injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1401
Route of Administration	INTRAVENOUS, INTRAVASCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	IODINE	140 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:0407-1401-52	10 in 1 BOX	05/25/2004	
1		50 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	NDA018956	05/25/2004	

OMNIPAQUE

iohexol injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1411
Route of Administration	ORAL, RECTAL, INTRATHECAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	IODINE	180 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:0407-1411-10	10 in 1 BOX	07/15/2004	
1		10 mL in 1 VIAL, GLASS; Type 0: Not a		

1		Combination Product		
2	NDC:0407-1411-20	10 in 1 BOX	07/15/2004	09/21/2025
2		20 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018956	07/15/2004	

OMNIPAQUE

iohexol injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1412
Route of Administration	INTRAVENOUS, INTRAVASCULAR, ORAL, RECTAL, INTRATHECAL, INTRA-ARTICULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	IODINE	240 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:0407-1412-10	10 in 1 BOX	12/26/1985	
		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination		

1		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0407-1412-20	10 in 1 BOX	12/26/1985	
2		20 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
3	NDC:0407-1412-50	10 in 1 BOX	12/26/1985	08/09/2012
3		50 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
4	NDC:0407-1412-29	10 in 1 BOX	12/26/1985	07/31/2016
4		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:0407-1412-30	10 in 1 BOX	12/26/1985	
5		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:0407-1412-60	10 in 1 BOX	12/26/1985	08/08/2012
6		100 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
7	NDC:0407-1412-33	10 in 1 BOX	12/26/1985	
7		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:0407-1412-27	10 in 1 BOX	12/26/1985	07/31/2011
8		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:0407-1412-49	10 in 1 BOX	12/26/1985	05/13/2011
9		150 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
10	NDC:0407-1412-34	10 in 1 BOX	12/26/1985	03/04/2025
10		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:0407-1412-28	10 in 1 BOX	12/26/1985	02/27/2012
11		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:0407-1412-35	10 in 1 BOX	12/26/1985	10/24/2024
12		200 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	NDA018956	12/26/1985	

OMNIPAQUE

iohexol injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1413
Route of Administration	INTRAVENOUS, INTRAVASCULAR, ORAL, RECTAL, INTRATHECAL, INTRA-ARTICULAR		

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:0407-1413-11	10 in 1 BOX	12/26/1985	08/22/2012
1		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0407-1413-10	10 in 1 BOX	12/26/1985	
2		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
3	NDC:0407-1413-59	10 in 1 BOX	12/26/1985	
3		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0407-1413-30	10 in 1 BOX	12/26/1985	02/27/2011
4		30 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
5	NDC:0407-1413-50	10 in 1 BOX	12/26/1985	08/09/2012
5		50 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
6	NDC:0407-1413-51	10 in 1 BOX	12/26/1985	11/21/2012

6		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
7	NDC:0407-1413-61	10 in 1 BOX	12/26/1985	
7		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:0407-1413-95	10 in 1 BOX	12/26/1985	05/14/2013
8		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
9	NDC:0407-1413-98	10 in 1 BOX	12/26/1985	07/31/2016
9		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:0407-1413-62	10 in 1 BOX	12/26/1985	02/26/2025
10		75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:0407-1413-99	10 in 1 BOX	12/26/1985	10/15/2010
11		75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:0407-1413-60	10 in 1 BOX	12/26/1985	02/21/2012
12		100 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
13	NDC:0407-1413-63	10 in 1 BOX	12/26/1985	
13		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:0407-1413-91	10 in 1 BOX	12/26/1985	07/31/2016
14		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
15	NDC:0407-1413-53	10 in 1 BOX	12/26/1985	
15		125 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
16	NDC:0407-1413-90	10 in 1 BOX	12/26/1985	01/24/2013
16		150 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
17	NDC:0407-1413-65	10 in 1 BOX	12/26/1985	
17		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
18	NDC:0407-1413-92	10 in 1 BOX	12/26/1985	07/31/2016
18		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
19	NDC:0407-1413-66	10 in 1 BOX	12/26/1985	02/19/2025
19		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
20	NDC:0407-1413-93	10 in 1 BOX	12/26/1985	08/30/2012
20		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
21	NDC:0407-1413-96	10 in 1 BOX	12/26/1985	11/04/2013

21		100 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
22	NDC:0407-1413-69	10 in 1 BOX	03/23/2020	02/20/2025
22		125 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	NDA018956	12/26/1985	

OMNIPAQUE

iohexol injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1414
Route of Administration	INTRAVENOUS, INTRAVASCULAR, ORAL, INTRA-ARTICULAR		

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:0407-1414-21	10 in 1 BOX	12/26/1985	07/31/2016

1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0407-1414-50	10 in 1 BOX	12/26/1985	03/01/2013
2		50 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
3	NDC:0407-1414-51	10 in 1 BOX	12/26/1985	12/17/2012
3		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:0407-1414-52	10 in 1 BOX	12/26/1985	01/25/2013
4		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
5	NDC:0407-1414-89	10 in 1 BOX	12/26/1985	
5		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:0407-1414-20	10 in 1 BOX	12/26/1985	07/31/2016
6		75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:0407-1414-90	10 in 1 BOX	12/26/1985	
7		75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:0407-1414-22	10 in 1 BOX	12/26/1985	07/31/2016
8		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:0407-1414-53	10 in 1 BOX	12/26/1985	12/05/2012
9		100 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
10	NDC:0407-1414-60	10 in 1 BOX	12/26/1985	12/17/2012
10		100 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
11	NDC:0407-1414-91	10 in 1 BOX	12/26/1985	
11		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:0407-1414-76	10 in 1 BOX	12/26/1985	
12		125 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
13	NDC:0407-1414-03	10 in 1 BOX	12/26/1985	01/25/2013
13		150 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
14	NDC:0407-1414-23	10 in 1 BOX	12/26/1985	07/31/2016
14		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
15	NDC:0407-1414-93	10 in 1 BOX	12/26/1985	
15		150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
16	NDC:0407-1414-04	10 in 1 BOX	12/26/1985	01/25/2013

16		200 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
17	NDC:0407-1414-94	10 in 1 BOX	12/26/1985	
17		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
18	NDC:0407-1414-24	10 in 1 BOX	12/26/1985	05/06/2013
18		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
19	NDC:0407-1414-80	10 in 1 BOX	12/26/1985	01/05/2011
19		250 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
20	NDC:0407-1414-95	10 in 1 BOX	03/23/2020	03/08/2025
20		125 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	NDA018956	12/26/1985	

OMNIPAQUE

iohexol solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1415
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	IODINE	9 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:0407-1415-09	10 in 1 BOX	04/27/2018	
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	NDA018956	04/27/2018	

OMNIPAQUE

iohexol solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0407-1416
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Iohexol (UNII: 4419T9MX03) (Iohexol - UNII:4419T9MX03)	IODINE	12 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:0407-1416-12	10 in 1 BOX	04/27/2018	
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	NDA018956	04/27/2018	

Labeler - GE Healthcare Inc. (053046579)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Shanghai, Co., Ltd.		545292716	MANUFACTURE(0407-1412, 0407-1413, 0407-1414)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare AS		515048908	MANUFACTURE(0407-1411, 0407-1412, 0407-1413, 0407-1414)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Ireland		988006565	MANUFACTURE(0407-1401, 0407-1411, 0407-1412, 0407-1413, 0407-1414, 0407-1415, 0407-1416)

Establishment

Name	Address	ID/FEI	Business Operations
GE Healthcare Lindesnes		518890970	API MANUFACTURE(0407-1401, 0407-1411, 0407-1412, 0407-1413, 0407-1414, 0407-1415, 0407-1416)

Revised: 5/2023 GE Healthcare Inc.