Converting Volume to Total Grams of Iodine — Omnipaque™ (iohexol)

Omnipaque Intravascular Injection

Concentration	50 mL	60 mL	70 mL	80 mL	90 mL	100 mL	110 mL	120 mL	130 mL	140 mL	150 mL	160 mL	170 mL	180 mL	190 mL	200 mL	210 mL	220 mL	230 mL	240 mL	250 mL
240 mg I/mL	12 g I	14.4 g I	16.8 g I	19.2 g I	21.6 g I	24 g I	26.4 g I	28.8 g I	31.2 g I	33.6 g I	36 g I	38.4 g I	40.8 g I	43.2 g I	45.6 g I	48 g I	50.4 g I	52.8 g I	55.2 g I	57.6 g I	60 g I
300 mg I/mL	15 g I	18 g I	21 g I	24 g I	27 g I	30 g I	33 g I	36 g I	39 g I	42 g I	45 g I	48 g I	51 g I	54 g I	57 g I	60 g I	63 g I	66 g I	69 g I	72 g I	75 g I
350 mg I/mL	17.5 g I	21 g I	24.5 g I	28 g I	31.5 g I	35 g I	38.5 g I	42 g I	45.5 g I	49 g I	52.5 g I	56 g I	59.5 g I	63 g I	66.5 g I	70 g I	73.5 g I	77 g I	80.5 g I	84 g I	87.5 g I

Omnipaque Oral Solution [to be used in conjunction with Intravenous Omnipaque Injection]

Concentration	180 mL	200 mL	250 mL	300 mL	350 mL	400 mL	450 mL	500 mL	550 mL	600 mL	650 mL	700 mL	750 mL	800 mL	850 mL	900 mL	950 mL	1000 mL
9 mg I/mL	1.6 g I	1.8 g I	2.3 g I	2.7 g I	3.2 g I	3.6 g I	4.1 g I	4.5 g I	5.0 g I	5.4 g I	5.9 g I	6.3 g I	6.8 g I	7.2 g I	7.7 g I	8.1 g I	8.6 g I	9.0 g I
12 mg I/mL	2.2 g I	2.4 g I	3.0 g I	3.6 g I	4.2 g I	4.8 g I	5.4 g I	6.0 g I	6.6 g I	7.2 g I	7.8 g I	8.4 g I	9.0 g I	9.6 g I	10.2 g I	10.8 g I	11.4 g I	12.0 g I

g I, grams of iodine

IMPORTANT SAFETY INFORMATION ABOUT OMNIPAQUE

WARNING: RISKS WITH INADVERTENTINTRATHECAL ADMINISTRATION OF 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.

Please see additional Important Safety Information on the following screens and consult the Full Prescribing information, here, for dosing volumes per specific indication.

GE HealthCare

OMNIPAQUE™ (IOHEXOL) INJECTION

INDICATIONS AND USE – OMNIPAQUE™ (IOHEXOL)

Intrathecal Administration – Adults: OMNIPAQUE 180, 240, and 300 • Myelography (lumbar, thoracic, cervical, total columnar) • Computed tomography (CT) (myelography, Intrathecal Administration – Adults: OMNIPAQUE 180, 240, and 300 • Myelography (lumbar, thoracic, cervical, total columnar) • Computed tomography (CT) (myelography, cisternography, ventriculography) **Pediatrics: OMNIPAQUE 180** • Myelography (lumbar, thoracic, cervical, total columnar) • CT (myelography, cisternography)

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.

Oral or Rectal Administration – Adults: OMNIPAQUE 350 • Oral radiographic examination of the gastrointestinal tract. **Pediatrics: OMNIPAQUE 180, 240, and 300** • Oral and rectal radiographic examinationof the gastrointestinal tract. **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 Solutions 9 and 12 administered orally in conjunction with OMNIPAQUE 300 administered intravenously** • CT of the abdomen. **Pediatrics: OMNIPAQUE Oral Solutions 9 and 12 administered orally in conjunction with OMNIPAQUE 240 or OMNIPAQUE 300 administered intravenously** • CT of the abdomen.

Intra-articular Administration – Adults: OMNIPAQUE 240, 300, and 350 • Arthrography.

Body Cavity Administration – Adults: OMNIPAQUE 240 • Endoscopic retrograde pancreatography (ERP) and endoscopic retrograde cholangiopancreatography (ERCP) • Herniography • Hysterosalpingography. **OMNIPAQUE 300** • Hysterosalpingography. **Pediatrics: OMNIPAQUE 240, 300, and 350 diluted** • Voiding cystourethrography (VCU).

IMPORTANT SAFETY INFORMATION ABOUT OMNIPAQUE™ (IOHEXOL)

WARNING: RISKS WITH INADVERTENTINTRATHECAL ADMINISTRATION OF 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.

CONTRAINDICATIONS:

- OMNIPAQUE 140 and OMNIPAQUE 350 are contraindicated for intrathecal use.
- OMNIPAQUE Oral Solutions 9 and 12 are contraindicated for parenteral administration.
- 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.

WARNINGS AND PRECAUTIONS:

- **Hypersensitivity Reactions:** Life-threatening or fatal hypersensitivity reactions, including anaphylaxis can occur. Most severe reactions develop within 3 minutes of injection start, but reactions can occur hours later. Increased risk exists in patients with previous reaction to contrast agents and known allergies (ie, bronchial asthma, drug, food allergies) or other hypersensitivities. Always have emergency resuscitation equipment and trained personnel available. Monitor all patients for hypersensitivity reactions.
- **Contrast-Induced Acute Kidney Injury:** Acute injury, including renal failure, may occur after parenteral administration. Risk factors include renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, and repetitive and/or large doses of an iodinated contrast agent. Minimize dose and maintain adequate hydration.
- **Cardiovascular Adverse Reactions:** Life-threatening or fatal cardiovascular reactions, including hypotension, shock, and cardiac arrest have occurred with the parenteral administration. Most deaths occur during injection or 5-10 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. Monitor all patients for severe cardiovascular reactions.
- **Thromboembolic Events:** Angiocardiography - Serious, rarely fatal, events causing myocardial infarction and stroke can occur during a procedure as increased thrombosis and activation of the complement system occurs. Risk factors include procedure length, catheter/syringe material, underlying disease, concomitant medications. Use meticulous angiographic techniques, minimize length of procedure. Avoid blood remaining in contact with syringes containing iodinated contrast agents. Avoid angiocardiography in patients with homocystinuria.

(Continued on following screen)

- **Extravasation and Injection-Site Reactions:** Extravasation 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, monitor patients for extravasation, and advise patients to seek medical care for progression of symptoms.
- **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.
- **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. Among patients 0 to 3 years of age exposed to iodinated contrast media, thyroid dysfunction has been reported in 1% to 15% depending on the age of the patient and the dose of the iodinated contrast agent. Monitor these patients for thyroid function abnormalities and treat as clinically needed.
- **Hypertensive Crisis in Patients With Pheochromocytoma:** Hypertensive crisis has occurred after the use of iodinated contrast agents in patients with pheochromocytoma. 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.
- **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.
- **Severe Cutaneous Adverse Reactions (SCARs):** SCARs may develop from 1 hour to several weeks after IV contrast administration. These 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 SCARs. Avoid administering to patients with a history of a SCAR to OMNIPAQUE.

ADVERSE REACTIONS:

- **Intrathecal:** Headaches, pain including backache, neckache, stiffness and neuralgia, nausea, vomiting, 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, heat sensation.
- **Postmarketing adverse events seen include:** Hypersensitivity and manifestations such as rash, pruritus, urticaria and dyspnea, chest pain, swelling.

DRUG-DRUG INTERACTIONS:

- **Metformin:** Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis, possibly as a result of worsening renal function in patients with renal impairment. Stop metformin at the time of, or prior to, injection of OMNIPAQUE. Reevaluate eGFR 48 hours after imaging procedure. 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.
- **Beta-Adrenergic Blocking Agents:** 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. 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.
- **Central Nervous System (CNS) Active Drugs:** Drugs like monoamine oxidase (MAO) inhibitors, tricyclic antidepressants, CNS stimulants, psychoactive drugs described as analeptics, major tranquilizers, or antipsychotic drugs 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 nonelective procedures in patients on these drugs, consider prophylactic use of anticonvulsants.

Please see full Prescribing Information, including boxed warning, here, for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

Customer Service 800 292 8514

Medical Affairs 800 654 0118 (option 2, then option 3) or medical.affairs@gehealthcare.com

Reimbursement Hotline 800 767 6664

gehealthcare.com

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OMNIPAQUE™
(IOHEXOL) INJECTION

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