GE HealthCare

Omnipaque™ (iohexol) injection

Approved since 1985, this low-osmolar iodinated contrast medium is indicated for intravenous, intra-arterial, intrathecal, intra-articular, body cavity, and oral use.[1]

Omnipaque is available in **20 different SKUs** to fit your needs.

OMNIPAQUE™ (IOHEXOL) SKU AVAILABILITY

Product		SKU	NDC
1123749	OMNIPAQUE 140mgI/mL USB 10x50 mL USA	Y-510	0407-1401-52
1114246	OMNIPAQUE 180mgI/mL VIAL 10x10 mL USA	Y-101	0407-1411-10
1123750	OMNIPAQUE 240mgI/mL USB 10x50 mL USA	Y-520	0407-1412-30
1123751	OMNIPAQUE 240mgI/mL USB 10x100 mL USA	Y-522	0407-1412-33
1114248	OMNIPAQUE 240mgI/mL VIAL10x10 mL USA	Y-203	0407-1412-10
1114249	OMNIPAQUE 240mgI/mL VIAL10x20 mL USA	Y-220	0407-1412-20
1114256	OMNIPAQUE 300mgI/mL VIAL 10x10 mL USA	Y-306	0407-1413-10
1123755	OMNIPAQUE 300mgI/mL USB 10x50 mL USA	Y-530	0407-1413-61
1123757	OMNIPAQUE 300mgI/mL USB 10x100 mL USA	Y-532	0407-1413-63
1123758	OMNIPAQUE 300mgI/mL USB 10x150 mL USA	Y-534	0407-1413-65
1172741	OMNIPAQUE 300mgI/mL USB 10x30 mL USA	Y-503	0407-1413-59
1123760	OMNIPAQUE 350mgI/mL USB 10x50 mL USA	Y-540	0407-1414-89
1123761	OMNIPAQUE 350mgI/mL USB 10x75 mL USA	Y-541	0407-1414-90
1123762	OMNIPAQUE 350mgI/mL USB 10x100 mL USA	Y-542	0407-1414-91
1123763	OMNIPAQUE 350mgI/mL USB 10x150 mL USA	Y-544	0407-1414-93
1123764	OMNIPAQUE 350mgI/mL USB 10x200 mL USA	Y-546	0407-1414-94
1188626	OMNIPAQUE 300mgI/mL USB IBP 10x500 mL USA	Y-538I	0407-1413-72
1188627	OMNIPAQUE 350mgI/mL USB IBP 10x500 mL USA	Y-548I	0407-1414-72
1190760	OMNIPAQUE 9mgI/mL USB 10x500 mL USA	RTD-09	0407-1415-09
1190761	OMNIPAQUE 12mgI/mL USB 10x500mL USA	RTD-12	0407-1416-12

Please click here to learn more about Omnipaque.

IMPORTANT SAFETY INFORMATION

WARNING: RISKS WITH INADVERTENT INTRATHECAL 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, hyperthemia, and brain edema.

Please see additional Important Safety Information on following page and full Prescribing Information, including Boxed Warning, here.

OMNIPAQUE™ (IOHEXOL) INJECTION

Reference: 1. Omnipaque [prescribing information]. Marlborough, MA: GE HealthCare. 2023.

CONTRAINDICATIONS:

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

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.
- **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.
- **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.

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