GE HealthCare

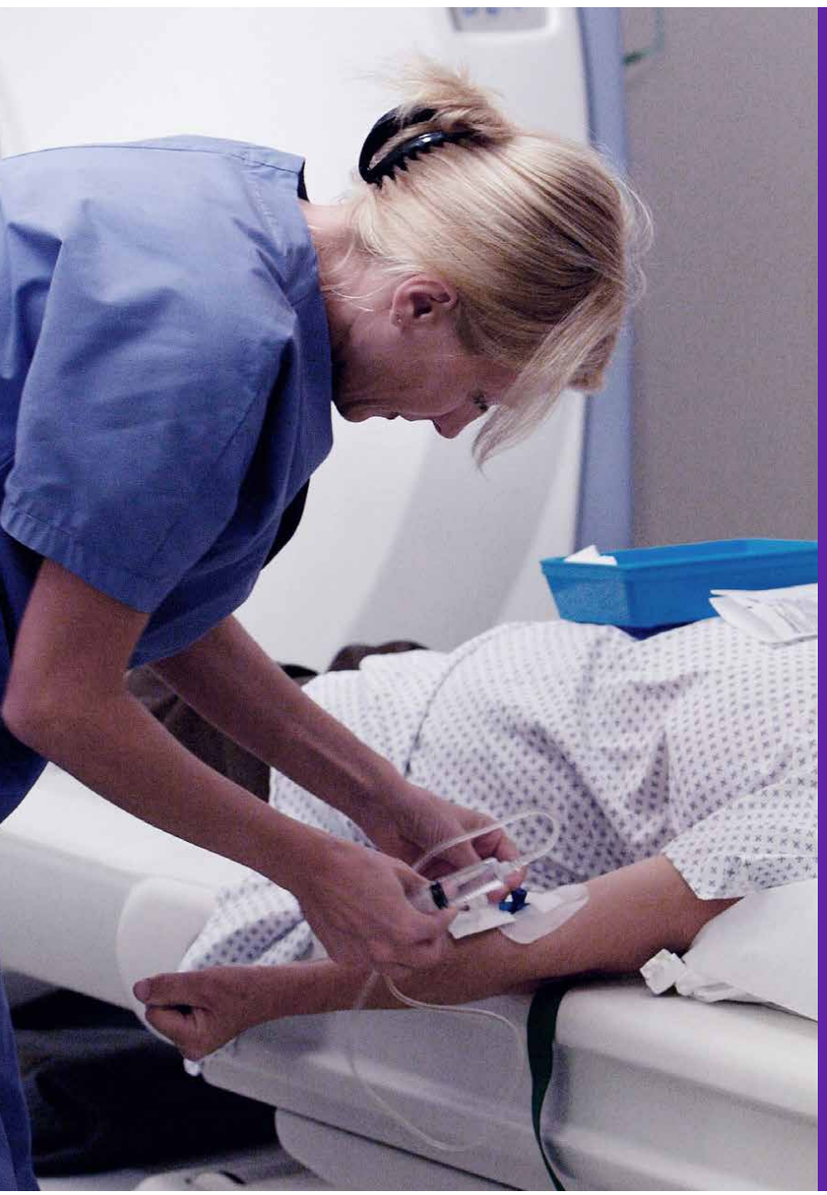
DELIVERING A BILLION TIMES OVER

OMNIPAQUE™
(IOHEXOL) INJECTION

BEYOND A BILLION PATIENT DOSES[1]

GE HealthCare

We've been delivering Omnipaque to customers around the world for more than 40 years.



Distinguished by a breadth of clinical data, a billion doses of Omnipaque is testament to the trust clinicians have in us to always deliver.

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“Four patient procedures a second are carried out using our imaging agents.[2] We have been producing and delivering contrast media for decades, dedicated to meeting the needs of customers and their patients.”

- Paritosh Dhawale, PhD
Chief Technology Officer

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Demand for iodinated contrast media, including Omnipaque, is expected to increase in the coming years.

We are committed to innovating and investing to meet future demand for iodinated contrast media and to ensuring security of supply so clinicians can plan care confidently.

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Product Indications and Clinical Use – Omnipaque™ (iohexol injection USP)

Adults: Subarachnoid: Omnipaque 240 (iohexol 240 mg I/mL) and Omnipaque 300 (iohexol 300 mg I/mL) are indicated for subarachnoid administration in adults for lumbar, thoracic, cervical and total columnar myelography. Delayed CT scans of the spinal subarachnoid space and of the intracranial CSF spaces may be obtained at the appropriate time following myelography, taking advantage of delayed opacification by the physiological cephalad circulation of the opacified CSF. Intravascular: Omnipaque 350 (iohexol 350 mg I/mL) is indicated in adults for left ventriculography, coronary arteriography, intravenous contrast enhancement for computed tomographic head and body imaging, peripheral arteriography, excretory urography, and intravenous digital subtraction arteriography. Omnipaque 300 (iohexol 300 mg I/mL) is indicated in adults for cerebral arteriography, intravenous contrast enhancement for computed tomographic head and body imaging, peripheral arteriography, peripheral venography, and excretory urography. Omnipaque 240 (iohexol 240 mg I/mL) is indicated in adults for intravenous contrast enhancement in computed tomographic head imaging, and for peripheral venography. Arthrography: Omnipaque 300 (iohexol 300 mg I/mL) or Omnipaque 240 (iohexol 240 mg I/mL) is recommended in adults for arthrography of the knee joint. Omnipaque 300 (iohexol 300 mg I/mL) is recommended for arthrography of the shoulder joint in adults. Oral: Omnipaque 300 and Omnipaque 350 are indicated in adults for oral administration for radiographic imaging of the gastrointestinal tract (including esophagus, stomach, small bowel and colon). Omnipaque 240, Omnipaque 300 and Omnipaque 350 diluted to 6 to 9 mg I/mL are indicated for oral administration in adults for CT of the abdomen and pelvis in conjunction with intravenous administration of Omnipaque.

Pediatrics: Intravascular: Omnipaque 350 (iohexol 350 mg I/mL) is indicated in children for angiocardiography. Omnipaque 300 (iohexol 300 mg I/mL) is indicated in children for excretory urography and may be used in infants for angiocardiography. Oral, Rectal, or by Enteric Tube: Omnipaque 240 and Omnipaque 300 are indicated for oral, rectal, or by enteric tube administration for radiographic imaging of the gastrointestinal tract (including esophagus, stomach, small bowel and colon). Omnipaque 240, Omnipaque 300 and Omnipaque 350 diluted to 9 to 29 mg I/mL are indicated for oral administration in children for CT of the abdomen and pelvis in conjunction with intravenous administration of Omnipaque.

CONTRAINDICATIONS

- Omnipaque (iohexol) is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Omnipaque is contraindicated in patients with clinically significant impairment of both hepatic and renal function.

SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- The possibility of hypersensitivity including serious, life-threatening, fatal anaphylactic/anaphylactoid reactions should always be considered. The majority of serious undesirable effects occur within the first 30 minutes. Late-onset (that is 1 hour or more after application) hypersensitivity reactions can occur. Patients should be observed for at least 30 minutes after administration of Omnipaque.
- Serious or fatal reactions have been associated with the administration of water-soluble contrast media. It is of utmost importance that a course of action be carefully planned in advance for immediate treatment of serious reactions, and that adequate facilities and appropriate personnel be readily available in case a severe reaction should occur.

- Concentration used: Use the recommended Omnipaque concentration for the particular procedure to be performed
- Caution is advised in patients with:
  - Sickle cell; fluid restriction is not advised in individuals who are homozygous for sickle cell disease
  - Multiple myeloma
  - Severe cardiovascular disease, hyperthyroidism, a history of bronchial asthma or other allergic manifestations, or sensitivity to iodine
  - Pheochromocytoma
  - Endotoxemia or elevated body temperature
- Elderly and pediatric patients may present a greater risk
- Thyroid dysfunction: Omnipaque, like all other iodinated contrast media, may induce changes in thyroid function in some patients. Transient hyperthyroidism or hypothyroidism has been reported following iodinated contrast media administration to adult and pediatric patients. Decreased levels of thyroxine (T4) and triiodothyronine (T3) and increased levels of TSH were reported after exposure to ICM in infants, especially preterm infants, which remained for up to a few weeks or more than a month. Hypothyroidism in infants may be harmful for growth and development, including mental development, and may require treatment
- Thyroid function should be checked in neonates following administration of iodinated contrast agents to mothers during pregnancy
- Contrast media-induced nephrotoxicity. Patients with pre-existing conditions that alter renal function are at increased risk
- Inaccurate thyroid function tests in the several weeks following radiopaque examination
- Potential for thyroid storm in patients with hyperthyroidism or autonomously functioning thyroid nodule
- Risk of severe adverse reactions in patients on adrenergic beta-blockers
- Risk of clinical deterioration, convulsions, and serious temporary or permanent neurological complications in patients with increased intracranial pressure, cerebral thrombosis or embolism, primary or metastatic cerebral lesions, subarachnoid hemorrhage, arterial spasm, transient ischemic attacks, and in any condition when the blood-brain barrier is breached or transit time of the contrast media through the cerebral vasculature is prolonged
- Caution in dose selection for patients with renal insufficiency
- Risk of acute renal failure in patients with pre-existing renal impairment, sepsis, hypotension, dehydration, advanced vascular disease, congestive heart disease, diabetes mellitus, multiple myeloma or other paraproteinacious diseases, the elderly with age-related renal impairment, and those on medications that alter renal function
- Patients should be adequately hydrated
- Safety and efficacy not established in pregnant women or those who are breastfeeding

Subarachnoid Use: Myelography should not be performed in the presence of infection; caution should be taken with patients on anticonvulsants and at risk of seizures.

Vascular Use: Serious thromboembolic events; patients with serum creatinine above 3 mg/dL; extreme caution with vasopressors; general anesthesia; metformin should be discontinued and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

Prior to administration, please read the Product Monograph for Omnipaque and the Important Safety Information About Iodinated Contrast Media, which is available by calling Customer Service 1 800 387 7146 or through an email request to canadainfo@ge.com.

Reporting Side Effects

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1 800 654 0118 (option 2, then option 1), or email canadainfo@ge.com to request an adverse events form, or fax to 905 847 5849 to request an adverse events form.

Adverse reactions can also be reported to Health Canada as follows:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

References:

1. GE HealthCare Data on File_Omnipaque and Visipaque Demand_2023
2. GE HealthCare Data on File_Patient Impact_2023.

JB01151CA/07-2024

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