Avoid the face with neutral taste

Omnipaque for Oral Use
Approved for use in adults and children

Omnipaque (IOHEXOL) Injection

Important Risk and Safety Information About Omnipaque

Oral Use is associated with mild, transient diarrhea, especially following high concentrations and volumes, which may result in hypovolemia. Plasma fluid loss may be sufficient to cause a shock-like state that, if untreated, could be dangerous, especially in the elderly, cachectic patients of any age, and infants and small children.
Neutral taste for your patients

- Shown to have a neutral taste when compared with ionic Gastrografin® (diatrizoate meglumine and diatrizoate sodium solution USP)²

- Omnipaque received a significantly better taste preference score than did MD-Gastroview® (diatrizoate meglumine and diatrizoate sodium solution USP) (P<0.001)³

![Taste preference graph]

Important Risk and Safety Information About Omnipaque

WARNINGS — Oral/Intravascular Use: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Omnipaque should be used with extreme care in patients with severe functional disturbances of the liver and kidneys, severe thyrotoxicosis, or myelomatosis. Diabetic patients with a serum creatinine level above 3 mg/dL should not be examined unless the possible benefits of the examination clearly outweigh the additional risk. Omnipaque is not recommended for use in patients with anuria. Contrast media are potentially hazardous in patients with multiple myeloma or other paraproteinemia. Ionic contrast media, when injected intravenously or intra-arterially, may promote sickling in individuals who are homozygous for sickle cell disease. Administration of contrast to patients known or suspected of having pheochromocytoma should be performed with extreme caution, and the dose injected should be kept to an absolute minimum. The patient’s blood pressure should be assessed throughout the procedure, and measures for the treatment of hypertensive crisis should be readily available. Incidences of thyroid storm have been reported following the use of iodinated, ionic contrast media in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Urography should be performed with caution in patients with severely impaired renal function and in patients with combined renal and hepatic disease.

Please see additional Important Risk and Safety Information About Omnipaque on pages 8-9.
Easy to drink

Omnipaque — a nonionic, low-osmolar contrast medium indicated for oral use in both adults and children¹

- Omnipaque is an oral contrast medium with a neutral taste that even kids will drink⁴
- Shown to have a neutral taste when compared with ionic diatrizoate²
- In a study of pediatric patients by Smevik and Westvik, 98% of children drank the entire dose⁵
- Patients in an abdominal computerized tomography study drank the entire prescribed amount and said they would do so again, if necessary⁶
- Provides good visualization of the intestines and is well suited for gastrointestinal (GI) use in infants and children⁷,⁸

Important Risk and Safety Information About Omnipaque

CONTRAINDICATIONS: Omnipaque should not be administered to patients with a known hypersensitivity to iohexol.

Please see additional Important Risk and Safety Information About Omnipaque on pages 8-9.
Omnipaque is an oral contrast medium that offers GI visualization with minimal GI side effects\(^2,6,8\)

- Omnipaque had a statistically significant, higher small bowel density than Gastrografin at one hour (\(P=0.007\)) and four hours (\(P=0.04\)) after ingestion\(^2\)

```
<table>
<thead>
<tr>
<th>Time</th>
<th>Omnipaque Density</th>
<th>Gastrografin Density</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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<td>Medium</td>
</tr>
<tr>
<td>8 hours</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
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- Particularly useful when iodinated high-osmolar contrast media is not appropriate or when barium sulfate is contraindicated, as in patients with suspected bowel perforation or those where aspiration of contrast medium is a possibility\(^1,7\)

Please read the enclosed Full Prescribing Information prior to administering Omnipaque for oral use in adults or children.

**Important Risk and Safety Information About Omnipaque**

**CONTRAINDICATIONS:** Omnipaque should not be administered to patients with a known hypersensitivity to iohexol.

Please see additional Important Risk and Safety Information About Omnipaque on pages 8-9.
Omnipaque for oral administration may be diluted as follows:\(^1\):

<table>
<thead>
<tr>
<th>To Achieve</th>
<th>Add</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>One liter of contrast medium at a final concentration of (mgI/mL)</td>
<td>Stock concentration of Omnipaque (mgI/mL)</td>
<td>Volume (mL)</td>
</tr>
<tr>
<td>6</td>
<td>240</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>300</td>
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</tr>
<tr>
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<td>350</td>
<td>60</td>
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</table>

Dilutions of Omnipaque should be prepared just prior to use and any unused portion discarded after the procedure. See the enclosed Full Prescribing Information for complete oral dosing and administration guidance.
Product codes and national drug codes (NDCs)

<table>
<thead>
<tr>
<th>Product code</th>
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<tr>
<td>Y520</td>
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<td>Y503</td>
<td>0407-1413-59</td>
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<td>0407-1413-61</td>
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<tr>
<td>Y540</td>
<td>0407-1414-89</td>
</tr>
</tbody>
</table>

Product codes listed are most commonly used for oral administration. For a full list of available Omnipaque product codes, please:

- Contact your local GE Healthcare Contrast Media Sales Specialist
- Contact GE Healthcare Customer Service at 800 292 8514
- Visit www.gehealthcare.com/omnipaque
Study designs for referenced clinical studies


A randomized, double-blind, prospective, single-center study of diagnostic quality, adverse effects, and taste in consecutive pass-through examinations for gastrointestinal obstruction in adults, using 100 mL of oral (undiluted) iohexol 350 mgI/mL (N=25) or sodium diatrizoate 370 mgI/mL (N=25). Patient groups were similar except for the overrepresentation of women in the 50-to-60 and 60-to-70 age groups in the iohexol and sodium diatrizoate groups, respectively. Taste results were not reported for one patient taking iohexol and two patients who took sodium diatrizoate.

McNamara MM, Lockhart ME, Fineberg NS, Berland LL. Oral Contrast Media for Body CT: Comparison of Diatrizoate Sodium and Iohexol for Patient Acceptance and Bowel Opacification. AJR. 2010;195:1137-1141.

The McNamara study was a randomized, double-blind, prospective, single-center trial of taste rating (5-point Likert scale), diagnostic opacification score, and adverse events of abdominal–pelvic contrast enhanced CT of adults using 900 mL each of diluted oral solutions of iohexol (N=149; 9.0 g iodine) or diatrizoate sodium (151 enrolled; 148 available for analysis; 9.17 g iodine) in addition to intravenous iopamidol 370 mgI/mL. A separate direct, double-blind taste preference comparison was conducted in which patients compared 30 mL of each diluted agent using a 3-point scale (preferred A, or B, or no preference). Patient age groups were similar.


A nonrandomized, observational, single-center study of radiographic quality and taste acceptance in 32 consecutive gastrointestinal examinations of infants and children (13 males and 19 females, aged 31 weeks to 13 years). Contrast was administered as iohexol 350 mg I/mL diluted to 7 mg I/mL and administered orally (120 to 500 mL), via gastric tube (60 to 300 mL), or rectally (60 to 120 mL) in pediatric patients (0 to 14 years of age). In 25 patients 3 mL/kg body weight of iohexol 350 mg I/mL was also administered intravenously. Taste was assessed in 20 patients and diagnostic quality, bowel enhancement, and safety in all 32. The undiluted strength and IV doses were greater than those specified in approved US labeling.


A nonrandomized, prospective, single-center study of contrast enhancement, taste, and microbiological quality in abdominal CT, with iohexol (7 mgI/mL, N=32 or 6 mgI/mL, N=128) diluted with water, juice, lemonade, or milk. Iohexol was administered orally (N=142), via feeding tube (N=5), or rectally (N=19) in pediatric patients (0 to 16 years of age); six patients received the drug both orally and rectally. Taste acceptance was recorded only for the 7-mgI/mL strength. Both strengths were less than the range specified in approved labeling and the 6-mgI/mL doses were prepared from vials of contrast left over from angiocardiology studies (stored from five days to two months). Oral dose volumes (0-1500 mL) were outside the range of approved US labeling. The concurrent dose of IV contrast was not specified.


A double-blind, randomized, prospective, single-center study of diagnostic quality, taste, and adverse experiences for 800 mL of three oral concentrations (4.5, 6.75, and 9 mgI/mL) of iohexol prepared from a 350-mgI/mL formulation. Subjects were adult patients referred for abdominal CT. The taste and consistency of the contrast media were recorded on a visual analogue scale of 0% (poor acceptance) to 100% (good acceptance). The contrast media were ingested in four 200-mL portions, one every 40 minutes, during two hours prior to the CT examination. Patient demographics were similar between dose groups. The 4.5-mgI/mL dose is below the minimum in approved US labeling. The labeled concurrent intravenous dose of iohexol used was not identified.


A nonrandomized, observational, single-center study of radiographic quality and taste acceptance in gastrointestinal examinations, using iohexol at full strength (350 mgI/mL, N=4) or diluted with water (175 mgI/mL, N=29). Iohexol was administered orally (N=14; taste acceptance reported for 11), via feeding tube (N=17), or rectally (N=2) in pediatric patients (0 to 14 years of age). The strengths and doses were outside of those specified in approved US labeling. The concurrent dose of intravenous contrast was not specified.
INDICATIONS: Oral/Body Cavity Use — Adults: Omnipaque 350 is indicated for arthrography and oral pass-through examination of the gastrointestinal (GI) tract. Omnipaque 300 is indicated for arthrography and hysterosalpingography. Omnipaque 240 is indicated for arthrography, endoscopic retrograde pancreatography and cholangiopancreatography, herniography, and hysterosalpingography. Children: Omnipaque 300 is indicated for examination of the gastrointestinal (GI) tract. Omnipaque 240 is indicated for examination of the GI tract. Omnipaque 180 is indicated for examination of the GI tract. Omnipaque diluted to concentrations from 50 mgI/mL to 100 mgI/mL is indicated for voiding cystourethrography. Oral/IV Use: Oral Omnipaque diluted to concentrations from 9 mgI/mL to 21 mgI/mL (pediatric) or 6 mgI/mL to 9 mgI/mL (adult), administered orally in conjunction with Omnipaque 240 (pediatric) or 300 (pediatric and adult) administered intravenously, is indicated for use in contrast-enhanced computed tomography of the abdomen. CONTRAINDICATIONS: Omnipaque should not be administered to patients with a known hypersensitivity to iohexol. WARNINGS — Oral/Intravascular Use: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Omnipaque should be used with extreme care in patients with severe functional disturbances of the liver and kidneys, severe thyrotoxicosis, or myelomatosis. Diabetic patients with a serum creatinine level above 3 mg/dL should not be examined unless the possible benefits of the examination clearly outweigh the additional risk. Omnipaque is not recommended for use in patients with anuria. Contrast media are potentially hazardous in patients with multiple myeloma or other paraproteinemia. Ionic contrast media, when injected intravenously or intra-arterially, may promote sickling in individuals who are homozygous for sickle cell disease. Administration of contrast to patients known or suspected of having pheochromocytoma should be performed with extreme caution, and the dose injected should be kept to an absolute minimum. The patient’s blood pressure should be assessed throughout the procedure, and measures for the treatment of hypertensive crisis should be readily available. Incidences of thyroid storm have been reported following the use of iodinated, ionic contrast media in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Urography should be performed with caution in patients with severely impaired renal function and in patients with combined renal and hepatic disease. PRECAUTIONS — General: Patients should be well hydrated prior to and following administration of any contrast medium. The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid, cardiovascular (CV), or central nervous system reactions, should always be considered. The possibility of an idiosyncratic reaction in susceptible patients should always be considered. The susceptible population includes, but is not limited to, patients with a history of a previous reaction to contrast media, patients with a known sensitivity to iodine, and patients with a known clinical hypersensitivity such as bronchial asthma, hay fever, and food allergies. After parenteral administration of a contrast agent, competent personnel and emergency facilities should be available for at least 30 to 60 minutes, since severe, delayed reactions have occurred. Renal Impairment: Use in patients with hepatorenal insufficiency only if the possibility of benefit clearly outweighs the additional risk. Diabetic Patients: Acute renal failure has been reported in diabetic patients with diabetic nephropathy and in susceptible nondiabetic patients (often elderly with preexisting renal disease) following excretory urography. Congestive Heart Failure (CHF): The potential transitory increase in the circulatory osmotic load in patients with CHF requires caution during injection. These patients should be observed for several hours following the procedure to detect delayed hemodynamic disturbances. General anesthesia may be indicated in the performance of some procedures in selected adult patients; however, a higher incidence of adverse reactions has been reported in these patients. Angiography should be avoided whenever possible in patients with homocystinuria, because of the risk of inducing thrombosis and embolism.Selective coronary arteriography should be performed only in those patients in whom the expected benefits outweigh the potential risk. Repeat Procedures: If in the clinical judgment of the physician, 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. Nursing Mothers: It is not known to what extent iohexol is excreted in human milk. However, many injectable contrast agents are excreted unchanged in human milk. Although it has not been established that serious adverse reactions occur in nursing infants, caution should be exercised when intravascular contrast media are administered to nursing women. Bottle feedings may be substituted for breastfeedings for 24 hours following administration of Omnipaque.

(cont’d on following page)
Important Risk and Safety Information About Omnipaque™ (iohexol) Injection (cont’d)

**Pediatric Use:** Pediatric patients at higher risk of experiencing adverse events during contrast medium administration may include those having asthma, sensitivity to medication and/or allergens, CHF, a serum creatinine greater than 1.5 mg/dL, or those younger than 12 months of age. **ADVERSE REACTIONS — Oral Use:** Is associated with mild, transient diarrhea, especially following high concentrations and volumes, which may result in hypovolemia. Plasma fluid loss may be sufficient to cause a shock-like state that, if untreated, could be dangerous, especially in the elderly, cachectic patients of any age, and infants and small children. **General Reactions to Contrast Media:** Serious, life-threatening, and fatal reactions, mostly of CV origin, have been associated with the administration of all iodine-containing contrast media. Aseptic meningitis syndrome has been reported rarely. Profound mental disturbances have been reported rarely, usually consisting of various forms and degrees of aphasia, mental confusion, or disorientation. The onset is usually at eight to 10 hours and lasts for about 24 hours, without aftereffects. Rarely, persistent though transitory weakness in the leg or ocular muscles has been reported. Peripheral neuropathies have been rare and transitory. In general, the reactions, which are known to occur upon parenteral administration of iodinated contrast agents, are possible with any nonionic agent. The reported incidence of adverse reactions to contrast media in patients with a history of allergy is twice that of the general population. Patients with a history of previous reactions to a contrast medium are three times more susceptible than other patients. Most adverse reactions to injectable contrast media appear within one to three minutes after the start of injection, but delayed reactions may occur. The injection of contrast media is frequently associated with the sensation of warmth and pain, especially in peripheral angiography.

Prior to Omnipaque administration, please read the **Full Prescribing Information.**

CONTRAINDICATIONS—Intrathecal
OMNIPAQUE should not be administered to patients with a known hypersensitivity to iohexol. Myelography should not be performed in the presence of significant local or systemic infection where bacteremia is likely.

Intrathecal administration of corticosteroids with OMNIPAQUE is contraindicated. Because of the possibility of overdose, immediate repeat myelography in the event of technical failure is contraindicated (see DOSAGE AND ADMINISTRATION).

WARNINGS—General
SEVERE ADVERSE EVENTS—AND INADVERTENT INTRATHecal ADMINISTRATION
Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These serious adverse reactions include convulsions, cerebral or spinal edema, headache, urinary retention, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to ensure that OMNIPAQUE 140 and 350 are not administered intrathecally. (All other concentrations of OMNIPAQUE are approved for intravenous administration.)

If grossly bloody CSF is encountered, the possible benefits of a myelographic procedure should be considered in terms of the risk to the patient.

Caution is advised in patients with a history of epilepsy, severe cardiovascular disease, chronic alcoholism, or multiple sclerosis.

Elderly patients may present a greater risk following myelography. The need for the procedure in these patients should be evaluated carefully. Special attention must be paid to dose and concentration of the medium, hydration, and technique used.

Parenteral patients should be maintained on this therapy. Should a severe intravascular dexamethasone injection be considered in patients with a history of seizure activity who are not on anticonvulsant therapy, premedication with barbiturates should be considered.

Phytoplastic anticonvulsant treatment with barbiturates should be considered in patients with evidence of inadvertent intracranial entry of a large or concentrated bolus of the contrast medium since there may be an increased risk of seizure in such cases.

Drugs which lower the seizure threshold, especially phenothiazine derivatives, including those used for antipsychotic and antiemetic properties, are not recommended for use with OMNIPAQUE. Other drugs include MAO inhibitors, tricyclic antidepressants, CNS stimulants, and psychoactive drugs described as amphetamine-like, major tranquillizers, or antipsychotic drugs. While the contribution of these medications has not been established, the use of such drugs should be based on physician evaluation of potential benefits and potential risks. Physicians have discontinued these agents at least 4 hours before and for at least 48 hours postprocedure.

Care is required in patient management to prevent inadvertent intracranial entry of a large dose or concentrated bolus of the medium. Also, effort should be directed to avoid rapid dispersion of the material and accidental inadvertent injection of the medium (see PRECAUTIONS—General).

Intrathecal injection of corticosteroids with OMNIPAQUE is contraindicated.

Myelography should not be performed in the presence of significant local or systemic infection where bacteremia is likely.

Intrathecal administration of corticosteroids with OMNIPAQUE is contraindicated. Because of the possibility of overdose, immediate repeat myelography in the event of technical failure is contraindicated (see DOSAGE AND ADMINISTRATION).

Intrathecal injection in patients with active or latent systemic or local infection, including any of the conditions listed above, is contraindicated. Intrathecal injection of corticosteroids with OMNIPAQUE is contraindicated.

Intrathecal injection should not be performed in patients with active or latent systemic or local infection, including any of the conditions listed above, is contraindicated. Intrathecal injection of corticosteroids with OMNIPAQUE is contraindicated.
The most frequently occurring adverse reaction following myelography has been headache as follows:

- Headache: mild to 2.7 g
- Nausea was reported with an incidence of about 6%, and vomiting about 3%
- Chills, fever, profuse diaphoresis, pruritus, urticaria, nasal congestion, cortical loss of vision has been reported in association with convulsions. Ventricular block has been observed 1 to 10 hours after injection, and almost all occur within 24 hours. They are usually mild to severe or persistent for days. Headache is often accompanied by nausea and vomiting and tends to be more frequent and persistent in patients not optimally hydrated.

Transient alterations in vital signs may occur and their significance must be assessed on an individual basis. Those reactions reported in clinical studies with OMNIPAQUE are listed below in decreasing order of occurrence, based on clinical studies of 1513 patients.

Headache: most frequently occurring adverse reaction following myelography has been headache, with an incidence of approximately 18%. Headache may be caused by either a direct effect of the contrast medium or by CSF leakage at the dural puncture site. However, in managing the patient, it is important to rule out more severe causes of headache, such as sinusitis, meningitis, or cerebral hemorrhage, before instituting management than attempting to control possible CSF leakage (see PATIENT MANAGEMENT).

Nausea and Vomiting: Nausea was reported with an incidence of about 6%, and vomiting about 3% (see PATIENT MANAGEMENT). Maintaining normal hydration is very important. The use of phenothiazine antinauseants is not recommended. (See WARNINGS—General Reassurance to the patient that the nausea will usually disappear is all that is required.

Other Reactions: Other reactions occurring with an individual incidence of less than 0.1% included:

- Feeling of heaviness, hypotension, hypotension, sensation of heat, sweating, vertigo, loss of appetite, drowsiness, dizziness, pallor, paresthesia, difficulty in micturition, and neurological changes. All were transient and mild with no clinical sequelae.

General Adverse Reactions to Contrast Media

Physicians should remain alert for the occurrence of adverse effects in addition to those discussed above, particularly the following reactions which have been reported in the literature for other nonionic, water-soluble myelographic media, and rarely with iohexol. These have included, but are not limited to, convolution, allergic and bacteriological meningitis, and CNS and other neurological disturbances.

An anaphylactic reaction syndrome has been reported rarely (less than 0.01%). It was usually preceded by pruritus, urticaria, and flushing. Onset usually occurred within 10 to 20 minutes after injection. Prominent features were meningeal, fever, sometimes with ocular signs and motor and sensory changes. Examination of the CSF revealed an increased WBC count with a high protein content often with a low glucose level and with absence of organisms. The condition usually started to clear spontaneously about 10 hours after onset, with complete recovery over 2 to 3 days.

Allergy or idiosyncrasy: rash, pruritus, urticaria, angioedema, bronchospasm, asthma, anaphylaxis, and a case of Guillain-Barré syndrome.

CNS injection: Mild and transitory perceptual aberrations such as hallucinations, depersonalization, amnesia, hypermetria, amблиopia, aphasia, phoberia, perceptual hallucinations, hypnosis, amnesia, depression, hyperesthesia, visual or auditory or speech disturbances, confusion and disorientation. In addition, melolalia, vertigo, delusions, confusional states, paranoia, phobias, hallucinations, and mania. However, these reactions have been reported more frequently in patients with a history of psychiatric or neurological disturbance. The reported incidence of adverse reactions to contrast media in patients with a history of allergy is twice that of the general population. Patients with a history of previous reactions to a contrast medium are sometimes more susceptible than other patients. However, sensitivity to contrast media does not appear to increase with repeated examinations.

Adverse reactions to intrathecal contrast media appear within 1 to 5 minutes after the start of injection, but delayed reactions may occur.

OVERDOSAGE

Clinical consequences of overdose with OMNIPAQUE have not been reported. However, based on experience with other nonionic myelographic media, physicians should be alert to a potential increase in frequency and severity of CNS-mediated reactions. Even use of a recommended dose can produce effects tantamount to overdose, if incorrect management of the patient during or immediately following the procedure permits inadvertent early intracranial entry of a large portion of the medium.

5. Intrathecal LD₅₀ value of OMNIPAQUE in grams of iode per kilogram body weight is greater than 2.0 in mice.

DOSAGE AND ADMINISTRATION — Intrathecal

The volume and concentration of OMNIPAQUE 180, OMNIPAQUE 240, or OMNIPAQUE 300 to be administered will depend on the degree and extent of contrast required in the area(s) under examination and on the equipment and technique employed.

OMNIPAQUE 180 at a concentration of 180 mg/mL, OMNIPAQUE 240 at a concentration of 240 mg/mL, or OMNIPAQUE 300 at a concentration of 300 mg/mL to be administered will depend on the estimated volume of contrast medium which may be required for the procedure. A small amount of CSF may be removed to minimize distention of the subarachnoid spaces. The lumbar or cervical puncture needle may be removed immediately following injection since it is not necessary to remove OMNIPAQUE after injection into the subarachnoid space.

The recommended dose is 1 to 3 g and may be as follows:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Formulations</th>
<th>Concentration (mg/mL)</th>
<th>Volume (mL)</th>
<th>Dosage (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar</td>
<td>Myelography</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
<td>10-17</td>
</tr>
<tr>
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<td>OMNIPAQUE 240</td>
<td>240</td>
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<td>240 g</td>
<td>injection</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
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<tr>
<td>Cervical</td>
<td>Myelography</td>
<td>OMNIPAQUE 180</td>
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<td>7-10</td>
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<td>OMNIPAQUE 240</td>
<td>240</td>
<td>6-12.5</td>
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<td>injection</td>
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<td>300</td>
<td>6-10</td>
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<td>Total Cervical</td>
<td>Myelography</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
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<td>injection</td>
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<td>240</td>
<td>6-12.5</td>
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<tr>
<td>240 g</td>
<td>injection</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
</tr>
</tbody>
</table>

Pediatrics: the usual recommended total doses for lumbar, thoracic, cervical, and/or total columnar myelography by lumbar puncture in children are 0.36 g to 2.7 g (see table below). Actual volumes administered depend largely on age and the following guidelines are recommended:

<table>
<thead>
<tr>
<th>Age</th>
<th>Conc. (mg/mL)</th>
<th>Volume (mL)</th>
<th>Dosage (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to &lt; 3 mos.</td>
<td>0.6-0.72</td>
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<tr>
<td>3 to &lt; 36 mos.</td>
<td>0.72-1.44</td>
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<td></td>
</tr>
<tr>
<td>3 to 7 yrs.</td>
<td>0.9-1.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 to 13 yrs.</td>
<td>1.2-2.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 to 18 yrs.</td>
<td>1.0-2.7</td>
<td></td>
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</tr>
</tbody>
</table>

Withdrawal of contrast agents from their containers should be accomplished under aseptic conditions with sterile syringes. Spinal puncture must always be performed under sterile conditions.

Parenteral drug products should be inspected for particulate matter or discoloration prior to administration. If particulate matter or discoloration is present, do not use.

Repeat Procedures: If in the clinical judgment of the physician a single repeat or sequential examinations are required, a suitable interval of time between administrations should be observed to allow for normal clearance of the drug from the body. An interval of at least 48 hours should be allowed before repeat examination; however, whenever possible, 5 to 7 days is recommended.
The pharmacokinetics of iohexol in both normal and abnormal tissue have been shown to be characterized by an initial sharp fall in plasma concentration. Equilibration with the extracellular compartments is reached in about ten minutes; thereafter, the fall becomes slow. The degree of density enhancement is directly related to the iodine content in an administered dose of contrast medium permitting radiographic visualization of the internal structures until significant hemodilution occurs. Approximately 90% or more of the injected dose is excreted within the first 24 hours, with the peak urine concentrations occurring in the first hour after administration. Plasma and urine iohexol levels indicate that the iohexol body clearance is due primarily to renal clearance. An increase in the dose from 500 mg I/kg to 1500 mg I/kg does not significantly alter the clearance of the drug. The following pharmacokinetic values were observed following the intravenous administration of iohexol between 500 mg I/kg to 1500 mg I/kg to 16 adult human subjects: renal clearance—120 (86-162) ml/min, total body clearance—131 (98-163) ml/min, and volume of distribution—165 (108-219) ml/kg.

Renal accumulation is sufficiently rapid that the period of maximal opacification of the renal passages may begin as early as 1 minute after intravenous injection. Urograms become apparent in about 1 to 3 minutes with optimal contrast occurring between 5 to 15 minutes. In nephropathic patients is not a contraindication; however, special precautions are necessary. Partial dehydration of the patient to precipitation of the myeloma protein in the renal tubules. No form of therapy, including dialysis, can reverse this complication of the procedure, as well as for emergency treatment of severe reactions to the contrast medium. OMNIPAQUE (iohexol) Injection probably clears the placental barrier in humans by simple diffusion. It is not known to what extent iohexol is excreted in human milk. Animal studies indicate that iohexol does not cross an intact blood-brain barrier to any significant extent following intravascular administration.

### INDICATIONS AND USAGE, GENERAL—Intravascular

OMNIPAQUE 350 is indicated in adults for angiography (angiocardiography, selective coronary arteriography, aortography, and femoral arteriography), aortography including studies of the aortic root, aortic arch, ascending aorta, and its branches, contrast enhanced computed tomographic body imaging, intravenous digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels, and preprocedure evaluation for neurosurgical procedures. OMNIPAQUE 350 is indicated in children for angiography (angiocardiography, pulmonary arteriography, and venography), studies of the collateral arteries and arteriovenous, including the aorta, aortic arch, ascending and descending aorta. OMNIPAQUE 350 is indicated in adults for aortography including studies of the aortic arch, abdominal aorta and its branches, contrast enhancement for computed tomographic head and body imaging, cerebral arteriography, percutaneous and excretory urography. OMNIPAQUE 350 is indicated in children for angiocardiography (angiocardiography, pulmonary arteriography, and venography), studies of the collateral arteries and arteriovenous, including the aorta, aortic arch, ascending and descending aorta. OMNIPAQUE 240 is indicated in adults for contrast enhancement for computed tomographic head and peripheral venography.

### CONTRAINDICATIONS

OMNIPAQUE should not be administered to patients with a known hypersensitivity to iohexol.

### WARNINGS—General

Nonionic iodinated contrast media inhibit blood coagulation, in hamsters, less than iohexol contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media. Several, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. For these reasons, meticulous angiographic techniques can be recommended including close attention to guide wire and catheter manipulation, use of manifold systems and/or three-way stopcocks, frequent catheter flushing with heparinized saline solutions and minimizing the length of the procedure. The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of in vitro clotting.

OMNIPAQUE should be used with extreme care in patients with severe functional disturbances of the liver, especially those with cirrhosis. Interestingly, the clinical sequelae of cirrhosis are due to a reduced liver blood flow, and iohexol, or any other contrast medium, will be eliminated in the manner and at the rate in which it is eliminated in normal patients. Patients with cirrhosis may be given a significantly increased dose because of incomplete renal excretion.
Dyspnea, rhinitis, coughing, and laryngitis, with an individual incidence of 0.2%. Arrhythmias including PVCs and PACs (2%), angina/chest pain (1%), and with some antihistamines and many resin uptake vein cramp and thrombophlebitis following intravenous injection.

values of OMNIPAQUE (in grams of iodine per kilogram body weight) are 24.2 in pulmonary or laryngeal edema, bronchospasm, dyspnea; of shock is estimated to be 1 out of 20,000 (0.005 percent) patients. The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions is higher with angiocardiography than with other procedures. Cardiac decompensation, media does not appear to increase with repeated examinations.

minor, intermediate, and severe. The minor reactions are self-limited and of short duration; the severe reactions are life-threatening and treatment is urgent and mandatory. The reported incidence of adverse reactions occurring in patients with a history of allergy are twice that of the general population. Patients with a history of previous reactions to a contrast medium are three times more susceptible than other patients. However, sensitivity to contrast media does not appear to increase with repeated examinations. Most adverse reactions to injectable contrast media appear within 1 to 3 minutes after the start of injection, but delayed reactions may occur.

overdosage may occur. The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular systems. Symptoms may include hypotension, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatment of an overdose is directed toward the support of all vital functions, and prompt institution of symptomatic therapy. The intravenous LD50, values of OMNIPAQUE in grams of iodine per kilogram body weight are 24 ± 15.0 in rats.

the minimum dose of OMNIPAQUE necessary to obtain adequate visualization should be used. A lower dose may reduce the possibility of an adverse reaction. Most procedures do not require use of either the maximum volume or the highest concentration of OMNIPAQUE. The combination of volume administration and concentration of OMNIPAQUE to be used should be carefully individualized accounting for factors such as age, body weight, size of the vessel, degree and extent of opacification required, structure(s) or area to be examined, disease processes affecting the patient, and equipment and technique to be employed. The dose should be considered.

Sterile technique must be used in all vascular injections involving contrast media. Withdrawal of contrast agents from their containers should be accomplished under aseptic conditions. Sterile technique must be used with any invasive procedure. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contami- nation with traces of cleansing agents.

that solubility of radiopaque diagnostic agents be used at body temperature when injected. Parenteral products should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is present, do not use.

The intravenous LD50, values of OMNIPAQUE in grams of iodine per kilogram body weight are 24 ± 15.0 in rats.

DOSAGE AND ADMINISTRATION—General

As with all radiopaque contrast agents, the lowest dose of OMNIPAQUE necessary to obtain adequate visualization should be used. A lower dose may reduce the possibility of an adverse reaction. Most procedures do not require use of either the maximum volume or the highest concentration of OMNIPAQUE. The combination of volume administration and concentration of OMNIPAQUE to be used should be carefully individualized accounting for factors such as age, body weight, size of the vessel, degree and extent of opacification required, structure(s) or area to be examined, disease processes affecting the patient, and equipment and technique to be employed. The dose should be considered.

Sterile technique must be used in all vascular injections involving contrast media. Withdrawal of contrast agents from their containers should be accomplished under aseptic conditions. Sterile technique must be used with any invasive procedure. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contami- nation with traces of cleansing agents.

that solubility of radiopaque diagnostic agents be used at body temperature when injected. Parenteral products should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is present, do not use.

INDIVIDUAL INDICATIONS AND USAGE ANGIOCARDIOGRAPHY Pharmacology—Hemodynamic Changes

OMNIPAQUE 350 at a concentration of 350 mgI/mL is indicated in children for angiocardiography (ventriculography, pulmonary arteriography, and venography), and studies of the cardiac arteries.
The usual single injection dose is 1.0 mL/kg of OMNIPAQUE 350 and should not exceed 5.0 mL/kg.

In children, injection of 1.0 mL/kg may be repeated as necessary. When combined with selective coronary arteriography, the total administered volume should not exceed 250 mL of OMNIPAQUE 350 or 6.0 mL/kg up to a total volume of 291 mL of OMNIPAQUE 350.

Precautions

During administration of large doses of OMNIPAQUE 350, continuous monitoring of vital signs is desirable. Caution is advised in the administration of large volumes to patients with incipient heart failure because of the possibility of aggravating the preexisting condition. Hypotension should be corrected promptly. Special care related to dosage should be observed in patients with right ventricular failure, pulmonary hypertension, or stenotic pulmonary vascular lesions because the hemodynamic changes which may occur after injection into the heart right outflow tract. (See PRECAUTIONS—General.)

Pediatric patients at higher risk of experiencing adverse events during contrast medium administration may include those having asthma, a sensitivity to medication and/or allergies, congestive heart failure, a serum creatinine greater than 1.5 mg/dL or those less than 12 months of age.

Adverse Reactions

Cardiovascular system reactions in angiography included angina (8%), hypertension (2.5%), bradycardia (1.0%), and tachycardia (1.0%). (See ADVERSE REACTIONS: Intravascular—General.)

Dosage and Administration

The individual dose or volume should be determined by the size of the structure to be visualized, the anticipated degree of hemodilution, and valvar competence. Weight is a minor consideration in adults, but must be considered in infants and young children. The volume of each individual injection is a more important consideration than the total dosage used. When large individual volumes are administered, as in ventriculography and arteriography, it has been suggested that several minutes be permitted to elapse between each injection to allow for subsidence of possible hemodynamic disturbances.

The recommended single injection volume of OMNIPAQUE 350 for angiographic procedures in adults and recommended injection volumes of OMNIPAQUE 350 and OMNIPAQUE 300 for angiographic procedures in children are as follows:

- **Ventriculography**
  - **Adults:** The usual adult volume for a single injection is 40 mL with a range of 30 mL to 60 mL. This may be repeated as necessary. When combined with selective coronary arteriography, the total administered volume should not exceed 250 mL (87.5 g).
  - **Pediatrics:** The usual single injection dose of OMNIPAQUE 350 is 1.25 mL/kg of body weight with a range of 1.0 mL/kg to 1.5 mL/kg. For OMNIPAQUE 300 the usual single injection dose is 1.75 mL/kg with a range of 1.5 mL/kg to 2.0 mL/kg. When multiple injections are given, the total administered dose should not exceed 5.0 mL/kg up to a total volume of 250 mL of OMNIPAQUE 350 or up to a total volume of 291 mL of OMNIPAQUE 300.

- **Selective Coronary Arteriography**
  - The usual adult volume for right or left coronary arteriography is 5 mL range 3 mL to 14 mL per injection.

- **Aortic Root and Arch Study When Used Alone**
  - The usual adult single injection volume is 50 mL, with a range of 20 mL to 75 mL.

- **Pulmonary Arteriography**
  - **Pediatrics:** The usual single injection dose is 1.0 mL/kg of OMNIPAQUE 350.

Combined/angiographic Procedures

- **Multiple Procedures**
  - **Adults:** The visualization of multiple vascular systems and target organs is possible during a single radiographic examination of the patient.
  - **Large doses of OMNIPAQUE 350 were well tolerated in angiographic procedures requiring multiple injections.**
  - **The maximum total volume for multiple procedures should not exceed 250 mL of 350 mg/mL (87.5 g).**
  - **Pediatrics:** Visualization of multiple vascular systems and target organs is possible during a single radiographic examination of the patient.
  - **The maximum total dose for multiple injection procedures should not exceed 5.0 mL/kg up to a total volume of 250 mL of OMNIPAQUE 350 or 6.0 mL/kg up to a total volume of 291 mL of OMNIPAQUE 300.**

AORTOGRAPHY AND SELECTIVE VISCERAL ARTERIOGRAPHY

OMNIPAQUE 300 at a concentration of 350 mg/mL and OMNIPAQUE 350 at a concentration of 350 mg/mL are indicated in adults for use in aortography and selective visceral arteriography including studies of the aortic root, arch, ascending aorta, and abdominal aorta and its branches (iliac, mesenteric, renal, hepatic and splenic arteries).

OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in children for use in aortography including studies of the aortic root, arch, ascending and descending aorta.

Precautions

Under conditions of slowed aortic circulation there is an increased likelihood for aortography to cause muscle spasm. Occasional serious neurologic complications including seizures, drowwness, transient paresis, and mild disturbances in vision such as photomas of 1-second or less duration. Central nervous system reactions to angiography included photomas (15%), headache (5.5%), and pain (4.5%). (See ADVERSE REACTIONS: Intravascular—General.)

Contraindications

OMNIPAQUE 300 is recommended for cerebral arteriography at the following volumes: common carotid artery (6 mL to 12 mL), external carotid artery (6 mL to 9 mL), and vertebral artery (6 mL to 10 mL).

CONTRAST ENHANCED COMPUTED TOMOGRAPHY

OMNIPAQUE 240 at a concentration of 240 mg/mL, OMNIPAQUE 300 at a concentration of 300 mg/mL, and OMNIPAQUE 350 at a concentration of 350 mg/mL are indicated in adults for use in intravascular contrast enhanced computed tomographic head and body imaging by rapid injection or infusion technique.

OMNIPAQUE 240 at a concentration of 240 mg/mL and OMNIPAQUE 300 at a concentration of 300 mg/mL are indicated in children for use in intravascular contrast enhanced computed tomographic head imaging by rapid bolus injection technique.

CT SCANNING OF THE HEAD

OMNIPAQUE may be used to redefine diagnostic precision in areas of the brain which may not otherwise have been satisfactorily visualized.

Tumors

OMNIPAQUE may be useful to investigate the presence and extent of certain malignancies such as gliomas including malignant gliomas, glialstomas, astrocytomas, oligodendrogliomas and gan-glioblastomas, medulloblastomas, meningomas, neurinomas, aneurysm, paraplyianomas, cerebellar astrocytomas, hemangioblastomas, gliomas, metastatic tumors, sarcomas, osteogenic sarcomas, chorionicephalic omomas, carcinopharyngiomas, germinomas, and metastatic lesions. The usefulness of contrast enhancement for the investigation of the retrolubar space and in cases of low grade or infiltrative glomas has not been demonstrated in clinical lesions. There is less likelihood of enhancement following therapy, tumors may show decreased or no enhancement. The opacification of the inferior venal and arterial systems may be obtained. "Contrast" media administration has resulted in false-positive diagnosis in a number of otherwise normal studies.

Nonneoplastic Conditions

OMNIPAQUE may be beneficial in the image enhancement of nonneoplastic lesions. Cerebral infarction, recent cerebral embolism or thrombosis, and cardiac decompensation.

The concentration and volume required will depend on the equipment and imaging technique used.

OMNIPAQUE (iohexol) Injection

The dosage recommended for use in adults for contrast enhanced computed tomography is as follows:

- **Head Imaging** by Injection:
  - 70 mL to 150 mL in 121 to 464 g of OMNIPAQUE 300 (300 mg/mL)
  - 80 mL to 120 g of OMNIPAQUE 350 (350 mg/mL)

- **Body Imaging** by Injection:
  - 50 mL to 200 mL in 115 to 600 g of OMNIPAQUE 300 (300 mg/mL)
  - 60 mL to 100 mL in 121 to 356 g of OMNIPAQUE 350 (350 mg/mL)

Diabetes and renal failure. A 10% single i.v. bolus of 2.4 mL/kg (145 mg/kg) of OMNIPAQUE 240 imaging 1:0 mL/kg to 2.0 mL/kg for OMNIPAQUE 240 or OMNIPAQUE 300. It should not be necessary to exceed a maximum dose of 28 g with OMNIPAQUE 240 or 35 g with OMNIPAQUE 300.

DIGITAL SUBTRATION ANGIOGRAPHY

Intravenous Administration

OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in intravenous digital subtraction angiography (IV/DSA) of the vessels of the head, neck, and abdominal, renal and peripheral arteries.

Arteriograms of diagnostic quality can be obtained following the intravenous administration of contrast media employing digital subtraction and computer imaging enhancement techniques. The intravenous route of administration using these techniques has the advantage of being less invasive than the corresponding selective catheter placement of medium. The dose is administered to a
OMNIpaque (iohexol) Injection

Peripheral venous access is required. The technique of injection has been described in Section II, Administration.

ADVERSE REACTIONS

Central nervous system reactions in intravascular angiography include transient ischemic attacks (1.6%) and cerebral infarctions (1.6%). These occurred in high risk patients having a cerebral vascular accident the relationship to the contrast medium was uncertain. (See ADVERSE REACTIONS—General.) Headache occurred in 6.3% of patients, all of whom were having cerebral examinations.

Intra-arterial Administration

OMNIPAQUE 140 at a concentration of 140 mg/mL is indicated for use in intra-arterial digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels. The intra-arterial route of administration has the advantages of allowing a lower total dose of contrast agent since there is less conversion than with the intravenous route of administration. Patients with poor cardiac output would be expected to have better contrast enhancement following intra-arterial administration as compared with intravenous administration. A higher concentration of contrast agent may be needed to facilitate catheter placement under fluoroscopic control.

Precautions

High pressure intra-arterial injections may cause the rupture of smaller peripheral arteries. (See PRECAUTIONS—General.)

Adverse Reactions

Central nervous system reactions include transient ischemic attacks and cerebral infarctions. Other unusual reactions include fever, muscle weakness, burning, unwell feeling, tremors, lightheadedness, syncope and convulsions.

PERIPHERAL ANGIOGRAPHY

OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in peripheral arteriography. OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in adults for use in peripheral venography. Sedative medication should be employed prior to use. Anesthesia is not considered necessary. Patient comfort during and immediately following injection is substantially less than that following injection of various other contrast media. Moderate to severe discomfort is a usual reaction.

Precautions

Pulsion should be present in the artery to be injected. In thrombocytopenia, obliterans, or ascending infection associated with severe sepsis, angiography should be performed with extreme caution, if at all. (See PRECAUTIONS—General.)

Adverse Reactions

A transient sensation of mild warmth is usual, immediately following injection. This has not interfered with the procedure. In phlebography the incidence of leg pain was 21%. This usually was mild and lasted a short time after injection. (See ADVERSE REACTIONS—General.)

Dosage and Administration

The volume and rate of injection will depend on the type of equipment, technique used, and the arterial system to be visualized. The following volumes and rates of injection have been used with OMNIPAQUE 140.

<table>
<thead>
<tr>
<th>Arteries</th>
<th>Volume/Injection (mL)</th>
<th>Rate of Injection (mL/sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic</td>
<td>10-20</td>
<td>1-3</td>
</tr>
<tr>
<td>Carotid</td>
<td>5-10</td>
<td>3-6</td>
</tr>
<tr>
<td>Femoral</td>
<td>9-20</td>
<td>3-6</td>
</tr>
<tr>
<td>Vertebral</td>
<td>4-10</td>
<td>2-8</td>
</tr>
<tr>
<td>Renal</td>
<td>6-12</td>
<td>3-4</td>
</tr>
<tr>
<td>Branches of the Aorta</td>
<td>8-20</td>
<td>3-10</td>
</tr>
</tbody>
</table>

PERIPHERAL ANGIOGRAPHY

OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in peripheral arteriography. OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in adults for use in peripheral venography. Sedative medication may be employed prior to use. Anesthesia is not considered necessary. Patient discomfort during and immediately following injection is substantially less than that following injection of various other contrast media. Moderate to severe discomfort is a usual reaction.

Precautions

Preparatory dehydration is not recommended in the elderly, infants, young children, diabetic or azotemic patients, or in patients with suspected myelogram.

Pediatric patients at high risk of experiencing adverse events during contrast medium administration may include those having a cardiac anomaly, chronic disease, trauma, or allergy, ischemic heart disease, a serum creatinine greater than 1.5 mg/dL, or those less than 12 months of age.

Since there is a possibility of temporary suppression of urine formation, it is recommended that a suitable interval elapse before excretory urography is repeated, especially in patients with unilateral or bilateral reduction in renal function. (See PRECAUTIONS—General.)

Adverse Reactions

See ADVERSE REACTIONS—Intravascular—General.

Dosage and Administration

Adults: OMNIPAQUE 300 and OMNIPAQUE 350 at dosages from 200 mg/kg body weight to 350 mg/kg body weight have produced diagnostic opacification of the excretory system in patients with normal renal function.

Pediatrics

Excretory Urography

OMNIPAQUE 300 at doses of 0.5 mL/kg to 3.0 mL/kg of body weight has produced diagnostic opacification of the excretory system in children. The usual dose for children is 1.5 mL/kg. Dosage for infants and children should be administered in proportion to age and body weight. The total administered dose should not exceed 3 mL/kg.

SECTION III

CLINICAL PHARMACOLOGY

Oral/Budy Cavity Use

For most body cavities, the injected iodine is absorbed into the surrounding tissue and eliminated by the kidneys and bowel as previously described in SECTION II, CLINICAL PHARMACOLOGY—Intravascular. Examinations of the uterus (hysterosalpingography) and bladder (cystourethrography) involve the almost immediate drainage of contrast medium from the cavity upon conclusion of the radiographic procedure.

Orally administered iohexol is very poorly absorbed from the normal gastrointestinal tract. Only 0.1 to 0.5 percent of the oral dose was excreted by the kidneys. This amount may increase in the presence of bowel obstruction. Iohexol is well tolerated and readily absorbed if leakage into the peritoneal cavity occurs. Visualization of the joint spaces, uterus, fallopian tubes, peritoneal herniations, pancreatic and bile ducts, and bladder can be accomplished by direct injection of contrast medium into the region to be studied. The use of appropriate iodine concentrations assures diagnostic density.

Orally administered OMNIPAQUE produces good visualization of the gastrointestinal tract. Iohexol is particularly useful when barium sulfate is contraindicated as in patients with suspected bowel perforation or those where aspiration of contrast medium is a possibility.

INDICATIONS AND USAGE, GENERAL—Oral/Budy Cavity Use

OMNIPAQUE 240, OMNIPAQUE 300, and OMNIPAQUE 350 have osmolalities from approximately 1.8 to 3.5 mOsm/kg of water and are hypotonic under conditions of use.

Adults: OMNIPAQUE 350 is indicated in adults for arthrography and oral pass-thru examination of the gastrointestinal tract.

OMNIPAQUE 300 is indicated in adults for arthrography and hysterosalpingography.

OMNIPAQUE 240 is indicated in adults for arthrography, endoscopic retrograde pancreatography and cholangiopancreatography, hysterosalpingography, and hysterosalpingography.

OMNIPAQUE diluted to concentrations from 6 mg/mL to 9 mg/mL administered orally in conjunction with OMNIPAQUE 300 at a concentration of 300 mg/mL administered intravenously is indicated in adults for contrast enhanced computed tomography of the abdomen.

Children: OMNIPAQUE 300 is indicated in children for examination of the gastrointestinal tract.

OMNIPAQUE 240 is indicated in children for examination of the gastrointestinal tract.

OMNIPAQUE 180 is indicated in children for examination of the gastrointestinal tract.

OMNIPAQUE diluted to concentrations from 50 mg/mL to 100 mg/mL administered orally in children for voiding cystourethrography.

OMNIPAQUE diluted to concentrations from 9 mg/mL to 21 mg/mL administered orally in conjunction with OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 300 at a concentration of 300 mg/mL administered intravenously is indicated in children for use in contrast enhanced computed tomography of the abdomen.

CONTRAINDICATIONS

OMNIPAQUE should not be administered to patients with a known hypersensitivity to iohexol.

WARNINGS—General

See SECTION II, WARNINGS—General.

PRECAUTIONS—General

Orally administered hypotonic injectable contrast media are associated with diarrhea which, if severe, could result in hypovolemia. Likewise, in infants and young children, the occurrence of diarrhoea may result in hypovolemia. Plasma fluid loss may be sufficient to cause a shock-like state which, if untreated, could be dangerous. This is especially pertinent to the elderly, cachectic patients of any age as well as infants and small children.

ADVERSE REACTIONS: Oral/Budy Cavity Use—General

Body Cavities

In controlled clinical trials involving 285 adult patients for various body cavity examinations using OMNIPAQUE 240, 300, and 350, the following adverse reactions were reported.

Cardiovascular System

Incidence > 1%: None
Incidence 1% to 10%: Hypertension
Incidence 1% to 0.1%: Headache, somnolence, fever, muscle weakness, burning, unwell feeling, tremors, lightheadedness, syncope
Respiratory System
None
Gastrointestinal System
Incidence > 1%: None
Incidence 1% to 0.1%: Flatulence, diarrhea, nausea, vomiting, abdominal pressure
Skin
Incidence > 1%: None
Incidence 1% to 0.1%: Prickly sensation, pruritus, rash
Other Adverse Reactions
Incidence > 1%: None
Incidence 1% to 0.1%: Bradycardia, tachycardia, tachypnea, dyspnea
None

EXCRETORY UROGRAPHY

OMNIPAQUE 300 at a concentration of 300 mg/mL or OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated for use in adults in excretory urography to provide diagnostic contrast of the urinary tract.

OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in children for excretory urography. (See Section III for information on voiding cystourethrography.) For pharmacokinetics of excretion in adults, see CLINICAL PHARMACOLOGY—Intravascular.

Precautions

Preparatory dehydration is not recommended in the elderly, infants, young children, diabetic or azotemic patients, or in patients with suspected myelogram.
OVERDOSAGE

The recommended dose of OMNIPAQUE 350 at a concentration of 350 mg/mL for adult oral pass-thru examination of the gastrointestinal tract is 50 mL to 100 mL. In a Phase I study, 150 mL of OMNIPAQUE 350 was administered orally to 11 healthy male subjects. The incidence of diarrhea was 91% (10 of 11) and abdominal cramping was 27% (3 of 11). Despite all of these events being mild and transient the adverse events were more than double that of the recommended doses. It is apparent from this finding that larger volumes of hypertonic contrast media, like OMNIPAQUE, increase the osmotic load in the bowel, which may result in greater fluid shifts.

DOSEAGE AND ADMINISTRATION—General

INDIVIDUAL INDICATIONS AND USAGE

Oral Use

Adults: OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in oral pass-thru examination of the gastrointestinal tract. OMNIPAQUE diluted to concentrations from 6 mg/mL to 9 mg/mL administered orally in conjunction with OMNIPAQUE 300 at a concentration of 300 mg/mL administered intravenously is indicated in adults for use in contrast enhanced computed tomography of the abdomen. Dilute oral plus intravenous OMNIPAQUE may be useful if unenhanced imaging does not provide sufficient delineation between normal loops of the bowel and adjacent organs or areas of suspected pathology.

Children: OMNIPAQUE 300 at a concentration of 300 mg/mL administered orally or rectally is indicated in children for use in examination of the gastrointestinal tract. OMNIPAQUE 180 at a concentration of 180 mg/mL administered orally or rectally is indicated in children for use in examination of the gastrointestinal tract. OMNIPAQUE diluted to concentrations from 9 mg/mL to 21 mg/mL administered orally in conjunction with OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 300 at a concentration of 300 mg/mL administered intravenously is indicated in children for use in contrast enhanced computed tomography of the abdomen.

Precautions

See PRECAUTIONS—General.

Adverse Reactions

Oral administration of OMNIPAQUE is most often associated with mild, transient diarrhea especially when high concentrations and large volumes are administered. Nausea, vomiting, and moderate diarrhea have been reported following orally administered OMNIPAQUE, but much less frequently. For CT examinations using dilute oral plus intravenous contrast medium, adverse events are more likely to be associated with the intrave nously administered hyperosmolar oral solution. It should be noted that serious or anaphylactoid reactions may occur with intravascular iodinated media are possible following administration by other routes. Adults: In controlled clinical trials involving 56 adult patients for oral pass-thru examination of the gastrointestinal tract using OMNIPAQUE 350, the following adverse reactions were reported: diarrhea (42%), nausea (15%), vomiting (11%), abdominal pain (7%), flatulence (2%), and headache (2%).

In controlled clinical studies involving 44 adult patients for dilute oral plus intravenous CT examination of the gastrointestinal tract using OMNIPAQUE 350, adverse reactions were limited to a single report of vomiting (1%).

Dosage and Administration

Adults: The recommended dose of undiluted OMNIPAQUE 350 at a concentration of 350 mg/mL for oral pass-thru examination of the gastrointestinal tract in adults is 50 mL to 100 mL depending on the nature of the examination and the size of the patient. The recommended oral dosage of OMNIPAQUE diluted to concentrations of 6 mg/mL to 9 mg/mL for contrast enhanced computed tomography of the abdomen in adults is 50 mL to 100 mL. Smaller administered volumes are needed as the concentration of the final solution is increased (see Table below). In conjunction with oral administration, the recommended dosage of OMNIPAQUE 300 administered intravenously is 100 mL to 150 mL. The oral dose is administered about 20 to 40 minutes prior to the intravenous dose and image acquisition.

Children: The dosage of undiluted OMNIPAQUE 300 at a concentration of 300 mg/mL, OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 180 at a concentration of 180 mg/mL is 50 mL to 150 mL. Higher volumes may be used in children 3 months of age and older. The following dosage guidelines are recommended:

<table>
<thead>
<tr>
<th>Age</th>
<th>Volume of OMNIPAQUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 months</td>
<td>5 – 30 mL</td>
</tr>
<tr>
<td>Three months to 3 years</td>
<td>Up to 60 mL</td>
</tr>
<tr>
<td>Four years to 10 years</td>
<td>Up to 80 mL</td>
</tr>
<tr>
<td>Greater than 10 years</td>
<td>Up to 100 mL</td>
</tr>
</tbody>
</table>

When given rectally, larger volumes may be used. The recommended oral dosage of OMNIPAQUE diluted to concentrations of 9 mg/mL to 21 mg/mL for contrast enhanced computed tomography of the abdomen in children is 50 mL to 100 mL depending on the nature of the examination and the size of the patient. The recommended oral dosage of OMNIPAQUE diluted to concentrations of 6 mg/mL to 9 mg/mL administered orally in conjunction with OMNIPAQUE 240 at a concentration of 240 mg/mL administered intravenously is 100 mL to 150 mL. The oral dose is administered about 20 to 40 minutes prior to the intravenous dose and image acquisition.

Children: The dosage of undiluted OMNIPAQUE 300 at a concentration of 300 mg/mL, OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 180 at a concentration of 180 mg/mL is 50 mL to 150 mL. Higher volumes may be used in children 3 months of age and older. The following dosage guidelines are recommended:

<table>
<thead>
<tr>
<th>Age</th>
<th>Volume of OMNIPAQUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 months</td>
<td>5 – 30 mL</td>
</tr>
<tr>
<td>Three months to 3 years</td>
<td>Up to 60 mL</td>
</tr>
<tr>
<td>Four years to 10 years</td>
<td>Up to 80 mL</td>
</tr>
<tr>
<td>Greater than 10 years</td>
<td>Up to 100 mL</td>
</tr>
</tbody>
</table>

When given rectally, larger volumes may be used. The recommended oral dosage of OMNIPAQUE diluted to concentrations of 9 mg/mL to 21 mg/mL for contrast enhanced computed tomography of the abdomen in children is 50 mL to 100 mL depending on the nature of the examination and the size of the patient. The recommended oral dosage of OMNIPAQUE diluted to concentrations of 6 mg/mL to 9 mg/mL administered orally in conjunction with OMNIPAQUE 240 at a concentration of 240 mg/mL administered intravenously is 100 mL to 150 mL. The oral dose is administered about 20 to 40 minutes prior to the intravenous dose and image acquisition.

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**OMNIPAQUE (iohexol) Injection**

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

**ENDOSCOPIC RETROGRADE PANCREATOGRAPHY (ERP)/ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP)**

OMNIPAQUE 240 at a concentration of 240 mg/mL is indicated in adults for use in ERP/ERCP.

### Adverse Reactions

Injection of OMNIPAQUE in ERP/ERCP is associated with transient pain. However, delayed, severe or persistent pain may occur and can persist for 24 hours. The cause of the pain may be due to much as to the procedure itself or to the contrast medium injected, therefore, attention should be paid to the injection pressure and total volume injected to minimize disruptive distention of the ducts examined. Cardiovascular system: Hypertension (1%). Nervous system: Pain (1%), somnolence (1%), and burning (1%). Gastrointestinal system: Vomiting, diarrhea, and pressure, each with an individual incidence of 1%

### Dosage and Administration

The recommended dose of OMNIPAQUE 240 at a concentration of 240 mg/mL is 10 mL to 50 mL but may vary depending on individual anatomy and/or disease state.

**HYSTEROSALPINGOGRAPHY**

OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in radiography of the internal group of adult female reproductive organs: ovaries, fallopian tubes, uterus, and vagina. Hysterosalpingography is utilized as a diagnostic and therapeutic modality in the treatment of infertility and other abnormal gynecological conditions.

### Contraindications

The procedure should not be performed during the menstrual period or when menstrual flow is imminent, nor should it be performed when infection is present in any portion of the genital tract including the external genitalia. The procedure is also contraindicated for pregnant women or for those in whom pregnancy is suspected. Its use is not advised for 6 months after termination of pregnancy or 30 days after conception or curettage.

### Precautions

In patients with carcinoma or in those in whom the condition is suspected, caution should be exercised to avoid possible spreading of the lesion by the procedure.

### Adverse Reactions

Injection of OMNIPAQUE in hysterosalpingography is associated with immediate but transient pain. However, delayed, severe or disruptive distention of the uterus and fallopian tubes. Fluoroscopic monitoring is recommended. Nervous system: Pain (4%), somnolence and fever each with an individual incidence of 3%. Gastrointestinal system: Nausea (3%).

### Dosage and Administration

The recommended dosage of OMNIPAQUE 240 is 15 mL to 20 mL and of OMNIPAQUE 300 is 15 mL to 20 mL but may vary depending on individual anatomy and/or disease state.

**HERNIOGRAPHY**

OMNIPAQUE 240 at a concentration of 240 mg/mL is indicated in adults for use in herniography.

### Adverse Reactions

Nervous system: Pain (7%), headache (3%), and unwell feeling (3%). Gastrointestinal system: Diarrhea (3%) and flatulence (10%).

### Dosage and Administration

The recommended dosage of OMNIPAQUE 240 is 50 mL but may vary depending on individual anatomy and/or disease state.

### HOW SUPPLIED

- **OMNIPAQUE 240**
  - 50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1401-52)
  - 150 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1412-27)
  - 200 mL fill in 250 mL bottle with hanger. 350 mg/mL, boxes of 10 (NDC 0407-1414-04)
  - 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-94)
  - 250 mL glass bottle, 350 mg/mL, boxes of 10 (NDC 0407-1414-80)

**FEDERAL GOVERNMENT CODES**

- **OMNIPAQUE 240**
  - 50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-29)
  - 150 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1412-27)
  - 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1412-28)

- **OMNIPAQUE 300**
  - 10 mL glass vial, 300 mg/mL, boxes of 10 (NDC 0407-1413-11)
  - 50 mL glass bottle, 300 mg/mL, boxes of 10 (NDC 0407-1413-95)
  - 50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-98)
  - 75 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-99)
  - 100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-91)
  - 150 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-92)
  - 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-93)

- **OMNIPAQUE 350**
  - 50 mL glass bottle, 350 mg/mL, boxes of 10 (NDC 0407-1414-52)
  - 100 mL glass bottle, 350 mg/mL, boxes of 10 (NDC 0407-1414-53)
  - 50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-21)
  - 75 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-20)
  - 100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-22)
  - 150 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-23)
  - 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-24)
  - Protect vials and glass or polymer bottles of OMNIPAQUE from strong daylight and direct exposure to sunlight. Do not freeze. OMNIPAQUE should be stored at controlled room temperature, 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

**SPECIAL HANDLING AND STORAGE FOR POLYMER BOTTLES ONLY:**

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