INTRATHECAL USE; SEVERE ADVERSE EVENTS DUE TO 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 reactions include death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to ensure that Omnipaque 140 and 350 are not administered intrathecally.

Before using Omnipaque, refer to the Full Risk and Safety Information available here and the Full Prescribing Information available here.
### Omniqua Product Codes and National Drug Codes (NDCs)

**+PLUSPAK™ (polymer bottle)**

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Omniqua 140 and Omniqua 350 are not for intrathecal use.

Before using Omniqua, refer to the Full Risk and Safety Information available here and the Full Prescribing Information available here.
Safety/Efficacy

- Introduced in 1986 — Omnipaque has been studied and used clinically for more than 30 years1
  - Published in thousands of trials and clinical studies
  - Approved for use in more than 100 countries1
- Versatile low-osmolar contrast with 39 approved indications, including2:
  - Indication for oral administration2
  - Indication for hysterosalpingography2
  - Intrathecal indication for myelography use2
  - Indications for the Cath Lab2

Omnipaque 140 mgI/mL and 350 mgI/mL are NOT FOR INTRATHECAL USE.

SEVERE ADVERSE EVENTS DUE TO 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 reactions include death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to insure that Omnipaque 140 and 350 are not administered intrathecally.

ADVERSE REACTIONS – Intrathecal Use: The most frequently reported adverse reactions with Omnipaque are headache, mild to moderate pain, including backache, neck ache and stiffness; nausea; and vomiting. Transient alterations in vital signs may occur. Oral Use is associated with mild, transient diarrhea, especially following high concentrations and volumes that may result in hypovolemia. General Reactions to Contrast Media: Serious, life-threatening, and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of all iodine-containing contrast media. Aseptic meningitis syndrome, profound mental disturbances, persistent transitory weakness in the leg or ocular muscles, and transitory peripheral neuropathies have been reported rarely. 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 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.


Before using Omnipaque, refer to the Full Risk and Safety Information available here and the Full Prescribing Information available here.
Packaging
• +PLUSPAK™ polymer bottle for enhanced workplace safety and efficiency
  – Eco-friendly, ecomagination™-certified product
• Extensive range of concentrations and volumes

Savings
• +PLUSPAK polymer bottles — Upfront price and waste disposal costs
• Competitive industry pricing — One-source solution with GE Healthcare
• Direct or through wholesaler of your choice

Support
• Medical Affairs: 800 654 0118 (option 2, then option 3)
• Reimbursement Hotline: 800 767 6664
• Customer Service: 800 292 8514
• www.gehealthcare.com
Important Risk and Safety Information About Omnipaque™ (iohexol) Injection

Omnipaque 140 mgI/mL and 350 mgI/mL are NOT FOR INTRATHECAL USE.

SEVERE ADVERSE EVENTS—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 reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to insure that Omnipaque 140 and 350 are not administered intrathecally.

INDICATIONS - Intravascular - Adults: Omnipaque 350 is indicated for angiocardiology [ventriculography, selective coronary arteriography, aortography, including studies of the aortic root, aortic arch, ascending aorta, abdominal aorta and its branches, contrast enhancement for computed tomographic (CT) head and body imaging, intravenous (IV) digital subtraction angiography (DSA) of the head, neck, abdominal, renal and peripheral vessels, peripheral arteriography, and excretory urography. Omnipaque 300 is indicated in adults for arteriography including studies of the aortic arch, abdominal aorta and its branches, contrast enhancement for CT head and body imaging, cerebral arteriography, peripheral venography (phlebography), and excretory urography. Omnipaque 240 is indicated for contrast enhancement for CT head imaging and peripheral venography (phlebography). Omnipaque 140 is indicated intra-arterial DSA of the head, neck, abdominal, renal and peripheral vessels. Children: Omnipaque 350 is indicated for angiocardiology (ventriculography, pulmonary arteriography, and venography; studies of the collateral arteries and aortography, including the aortic root, aortic arch, ascending and descending aorta). Omnipaque 300 is indicated for angiocardiology (ventriculography), excretory urography, and contrast enhancement for CT head imaging. Omnipaque 240 is indicated for contrast enhancement for CT head imaging. Intrathecal: - Adults: Omnipaque 180, 240, and 300 are indicated for intrathecal administration in adults including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for computerized (CT) (myelography, cisternography, ventriculography). Children: Omnipaque 180 is indicated for intrathecal administration in children including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for CT (myelography, cisternography). Oral/Body Cavity Use: Adults: Omnipaque 350 is indicated for arthrography and oral pass-thru 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 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. 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 overdosage, immediate repeat myelography in the event of technical failure is contraindicated.

WARNINGS: Intravascular and Oral 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. Diabetics 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
Important Risk and Safety Information About Omnipaque™ (iohexol) Injection (continued)

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. Reports 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 patients with combined renal and hepatic disease. Intrathecal Use: 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. Special attention must be paid to dose and concentration of the medium, hydration, and technique used. Drugs that lower the seizure threshold, especially phenothiazine derivatives, including those used for their antihistamine properties, are not recommended for use with Omnipaque. While the contributory role of these medications has not been established, the use of such drugs should be based on physician evaluation of potential benefits and potential risks. Direct intracisternal or ventricular administration for standard radiography (not CT) is not recommended.

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 per se, and patients with a known clinical hypersensitivity: 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. Diabetics: Acute renal failure has been reported in diabetic patients with diabetic nephropathy and in susceptible non-diabetic patients (often elderly with pre-existing 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 breast feedings for 24 hours following administration of Omnipaque. 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, congestive heart failure, a serum creatinine greater than 1.5 mg/dL or those less than 12 months of age.

ADVERSE REACTIONS—Intrathecal Use: The most frequently reported adverse reactions with Omnipaque are headache, mild to moderate pain including backache, neck ache and stiffness, nausea, and vomiting. These reactions usually occur 1 to 10 hours after injection, and almost all occur within 24 hours. Rarely, headaches may be severe or persist for days. Transient alterations in vital signs may occur and their significance must be assessed on an individual basis. 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 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 8 to 10 hours and lasts for about 24 hours, without after effects. 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 1 to 3 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 available here.**
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 overdosage, immediate repeat myelography in the event of technical failure is contraindicated (see DOSAGE AND ADMINISTRATION).

WARNINGS—General

SEVERE ADVERSE EVENTS—INADVERTENT INTRATHecal ADMINISTRATION

Severe 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 death, convulsions, cerebral edema, coagulation failure, cardiac arrest, seizures, thrombomylolysis, hyperthermia, and brain edema. Special attention must be given to ensure that OMNIPAQUE is not injected intrathecally. (All concentrations of OMNIPAQUE are approved for intrathecal 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 so forth.

Patients who are receiving anticonvulsants should be maintained on this therapy. Should a severe intraocular, intraventricular or subarachnoid hemorrhage is suspected, it is suggested that a thoracic medical history with emphasis on allergy and hypertension under conditions of use.

SECTION I

CLINICAL PHARMACOLOGY—Intrathecal

Iohexol is absorbed from cerebrospinal fluid (CSF) into the bloodstream and is eliminated by renal excretion. No significant metabolism, degradation, or biotransformation occurs.

In five adult volunteer subjects receiving 1.8 cc of iohexol (180 mg/mL) by lumbar intrathecal injection, approximately 88 (73.1-98.2) percent of the injected dose was excreted in the urine within the first 24 hours after administration. The renal and body clearances were 99 (47-137) ml/min per 1.73 m2 and 109 (52-138) ml/min per 1.73 m2. The mean maximal plasma concentration was 119 (72-177) micrograms of iohexol per milliliter and occurred after 4.8 (1.6-9.1) hours. The volume of distribution was 557 (350-841) ml/kg per literogram. In one patient with a large spinal cord tumor, excretion was delayed 67 percent of the dose appeared in the urine within the first 24 hours with no change in the total recovery in the urine after 48 hours. The delay in appearance occurred to be related to a decrease in the rate of transfer of iohexol from the cerebrospinal fluid to the blood (plasma maximal concentration was approximately 30 micrograms/mL).

The initial concentration and volume of the medium, in conjunction with appropriate patient manipulation and the volume of CSF into which the medium is placed, will determine the extent of distribution that can be achieved.

Following intrathecal injection in conventional radiography, OMNIPAQUE 180, OMNIPAQUE 240, and OMNIPAQUE 300 continue to provide good diagnostic contrast for at least 30 minutes. Slow diffusion of iohexol takes place throughout the CSF with subsequent absorption into the bloodstream. Once in the systemic circulation, iohexol displays little tendency to bind to serum or plasma proteins. At approximately 1 hour following injection, contrast of diagnostic quality will no longer be available for conventional tomography. If computerized tomographic (CT) myelography is to follow, consideration should be given to a delay of several hours to allow the degree of contrast to decrease. Patients with a previous history of severe allergic reactions to contrast media should always be considered (see ADVERSE REACTIONS). There-fore, it is of utmost importance that a course of action be carefully planned in advance for the immediate treatment of serious reactions and that adequate and appropriate facilities and personal- nnel be readily available in case of any reaction.

The possibility of an idiosyncratic reaction in susceptible patients should always be considered (see ADVERSE REACTIONS). The possibility of an anaphylactoid reaction includes but is not limited to patients with a history of a previous reaction to contrast media, patients with a known sensitivity to iohexol per se, and patients with a known clinical hypersensitivity: bronchial asthma, hay fever, and food allergies. The occurrence of severe idiosyncratic reactions has prompted the use of several pretesting methods. However, pretesting cannot be relied upon to predict severe reactions and may itself be hazardous to the patient. It is suggested that a thorough medical history with emphasis on allergy and hypersensitivity, prior to the injection of any contrast media, may be more accurate than pretesting in predicting potential adverse reactions. A positive history of allergies or hypersensitivity does not arbitrarily contraindicate the use of a contrast agent where a diagnostic procedure is thought essential, but caution should be exercised (see ADVERSE REACTIONS). Premedication with antihistamines or corticosteroids should avoid the minimize possible allergic reactions in such patients should be considered. Recent reports indicate that such premedication does not prevent serious life-threatening reactions, but may reduce both the incidence and severity of the reaction.

In patients with severe renal insufficiency or failure, compensatory bilateral excretion of the drug is anticipated to occur, with a slow clearance to occur. In patients with hepatic renal insufficiency should not be examined unless the possibility of benefit clearly outweighs the additional risk.

Administration of contrast media should be performed by qualified personnel familiar with the procedure and appropriate patient management (see PATIENT MANAGEMENT). Sterile technique must be used with any spinal puncture.

When OMNIPAQUE is to be injected using plastic disposable syringes, the contrast medium should be drawn into the syringe and used immediately.

If nondisposable equipment is used, scrubbed scrubs should be taken to prevent residual contamination with traces of cleansing agents.

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

Dose: Procedures: In the clinical treatment 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 (see DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY).
2. Inform your physician if you are diabetic or if you have multiple myeloma, phaeochromocytoma, homoygous sickle cell disease or known thyroid disorder (see WARNINGS).
3. Inform your physician if you are allergic to any drugs, foods, or if you had any reactions to previous administrations of IODINUM or other nonionic contrast media. See PRECAUTIONS—General.
4. Inform your physician about any other medications you are currently taking, including non-prescription drugs, before you are administered this drug.

Drug Interactions

Drugs which lower seizure threshold, especially phenothiazine derivatives including those used for their antihistaminic or antipsychotic properties, are not recommended for use with OMNIPAQUE. Others including carbamazepine, phenytoin, and primidone are also potential seizure-inducing agents. Psychopharmacologic drugs can cause depression or exacerbate pre-existing depression. Psychotropic drugs act as anxiolytics, major tranquilizers, or antipsychotic drugs. Such medications should be discontinued at least 1 week 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 postprocedure. In nonselective procedures in patients on these drugs, consider prophylactic use of anticonvulsants.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenesis, or impairment of fertility in men or women.

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits with up to 100 times the recommended human dose and have revealed no evidence of impaired fertility or harm to the fetus due to OMNIPAQUE. There are, however, no studies in pregnant women. Because animal reproduc tion studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

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 breast feedings following administration of OMNIPAQUE.

Pediatric Use

Pediatric patients at higher risk of experiencing adverse events in contrast medium administration may include those having a history of allergy, or having impaired fetal or neonatal development. These recommendations are based on the clinical trial evaluation to date. As in adults, the only reliable information available on the safety of OMNIPAQUE for use in children is derived from clinical trials in 1511 patients.

ADVERSE REACTIONS—Intrathecal

The most frequently reported adverse reactions with OMNIPAQUE are headache, mild to moderate pain, nausea, and vomiting. Other reactions include: yawn, sneeze, rhinorrhea, and flushing. These reactions usually occur 1 to 10 hours after injection, and almost all occur within 24 hours. They are usually mild to moderate and tend to be more frequent and persistent in patients not optimally hydrated.

Other reactions occurring with an individual incidence of less than 0.7% included:

1. Headaches may be severe or persist for days. Headache is often accompanied by nausea and vomiting and tends to be more frequent and persistent in patients not optimally hydrated.

Other Reactions occurring with an individual incidence of less than 0.7% included:

Pain: to mild moderate pain including backache, neckache, and stiffness, and neuralgia occurring following injection with an incidence of about 8%.

Nausea and Vomiting: Nausea was reported with an incidence of about 6%, and vomiting about 3% following injection with an incidence of about 8%.

Allergic or Idiosyncrasy:

The reported incidence of adverse reactions to contrast media in patients with a history of allergy is 2% to 6% 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 intrathecal contrast media appear within 1 to 3 minutes after the start of injection, but delayed reactions may occur.

OVERDOSAGE

Clinical consequences of overdosage with OMNIPAQUE have not been reported. However, based on experience with other x-ray contrast agents, the following measures may be considered:

1. Maintain normal hydration.
2. If abdominal distention becomes severe, analgesics, and if necessary, use of anticonvulsants.
3. Withhold use of antihistaminics.
4. Inform your physician about any other medications you are currently taking, including non-prescription drugs, before you are administered this drug.

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 are recommended for the administration of the lumbar, thoracic, and cervical regions in adults by lumbar or direct cervical injection and is slightly more suitable for use in the management of the subarachnoid space. OMNIPAQUE 180 at a concentration of 180 mg/mL is recommended for the examination of the lumbar, thoracic, and cervical regions in children by lumbar injection and is slightly hypocellular to CSF.

A total dose of 3060 mg iodine or a concentration of 300 mg/ml should not be exceeded in adults and 1530 mg iodine or a concentration of 180 mg/ml should not be exceeded in children in a single myelographic examination. This is based on clinical trial evaluation to date. As in diagnostic procedures, the minimum volume and dose to produce adequate visualization should be used. Miss procedures do not require either minimum dose or concentration. Anesthesia is not necessary. Premedication sedatives or tranquilizers are usually not needed (see PRECAUTIONS—General). In patients who will not be well hydrated prior to and following contrast administration. Severe-prone patients should be maintained on anticonvulsant medication.

Many radiopaque contrast agents are incompatible in vitro with some antihistamines and many other drugs; therefore, concurrent drugs should not be physically admixed with contrast injectates. Rate of Injection: To avoid excessive mixing with CSF and consequent dilution of contrast, injection should be made slowly over 1 to 2 minutes. Depending 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.

Adults: The usual recommended total doses for use in lumbar, thoracic, and cervical column myelography in adults are 1.2 to 3.0 g as follows:

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<td>Iva thoracic</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
<td>1.8-3.0</td>
</tr>
<tr>
<td>Iva cervical</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
<td>1.8-3.0</td>
</tr>
<tr>
<td>Cervical</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
<td>7-10</td>
<td>1.3-1.8</td>
</tr>
<tr>
<td>Iva lumbar</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
<td>1.8-3.0</td>
</tr>
<tr>
<td>Iva cervical</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
<td>1.8-3.0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Age</th>
<th>Volume</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to &lt; 3 mos</td>
<td>180</td>
<td>2-4</td>
</tr>
<tr>
<td>3 to 7 mos</td>
<td>180</td>
<td>4-8</td>
</tr>
<tr>
<td>7 to &lt; 1 yrs</td>
<td>180</td>
<td>5-10</td>
</tr>
<tr>
<td>1 to 10 yrs</td>
<td>180</td>
<td>9-12</td>
</tr>
<tr>
<td>10 to 18 yrs</td>
<td>180</td>
<td>10-15</td>
</tr>
</tbody>
</table>

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

Parenteral products should be inspected visually for particulate matter or discoloration prior to administration. In the event of discoloration, the solution should not be used.

Repeal Procedures: If in the clinical judgment of the physician the sequential or repeat examinations are required, a suitable interval of time between examinations 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.
of contrast medium within the interstitial tissue of the tumor. Adjacent normal brain tissue does not contain the contrast medium.

Maximum contrast enhancement in tissue frequently occurs after peak blood iodine levels are reached. Maximum in vivo contrast enhancement is seen in the first 5 to 10 minutes after injection, when contrast-enhanced images of the brain have been obtained up to 1 hour after intravenous bolus administration. This delay suggests that radiographic information obtained at least in part dependent on the accumulation of iodine containing medium within the lesion and outside the blood pool, although the mechanism by which this occurs is not clear. The radiographic enhancement of nonnal tissue due to nonarterous movement of contrast media may be dependent on the iodine content of the circulating blood pool.

In patients where the blood-brain barrier is known or suspected to be disrupted, the use of any radiographic contrast medium must be assessed on an individual risk to benefit basis. However, compared to iomyric media, nonionic media are less toxic to the central nervous system.

CT SCANNING OF THE HEAD

In contrast-enhanced computed tomographic topographic brain imaging, OMNIPAQUE diffuses rapidly from the vascular into the extracellular space. Increase in x-ray absorption is related to blood volume concentration of the contrast medium, and enhancement by interstitial tissue of tumors since no barrier exists. Contrast enhancement is thus due to the relative differences in x-ray absorption between normal and abnormal tissue, quite different from that in the brain.

INDICATIONS AND USAGE, GENERAL—Intravascular

OMNIPAQUE 350 is indicated in adults for angiography (angiography, selectivity, coaxial arteriography), aortography including studies of the aortic root, arch, and its branches, contrast enhancement for computed tomographic head and body imaging, intravenous digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels, peripheral arteriography, and excretory urography.

OMNIPAQUE 300 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, peripheral arteriography (pial, and excretory urography).

OMNIPAQUE 350 is indicated in children for angiography (angiography, selectivity, coaxial arteriography), excretory urography, and contrast enhancement for computed tomographic head imaging.

OMNIPAQUE 240 is indicated in adults for contrast enhancement for computed tomographic head imaging and peripheral venography, and excretory urography.

OMNIPAQUE 140 is indicated in adults for intra-arterial digital subtraction angiography of the head, neck, abdominal, renal and peripheral vessels.

OMNIPAQUE 240 is indicated in children for contrast enhancement for computed tomographic head imaging.

STORAGE AND HANDLING

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

WARNINGs—General

Nonionic iodinated contrast media inhibit blood coagulation, in vitro, less than ionic contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media.

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported with iodinated contrast agents. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. Numerous factors, including length of procedure, catheter and syringe material, underlying disease state, and concomitant medications, may contribute to the development of thromboembolic events. For these reasons, meticulous angiographic technique are recommended including close attention to guidewire and catheter manipulation, use of manifold systems and/or three-way stopcocks, frequent catheter flushing with heparinized saline solutions and monitoring 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 and kidneys, severe thyrotoxicosis, or myelomatosis. Diabetics 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. Myelomatous patients, with preexisting renal disease, infants and small children. Dehydration in these patients seems to be an important factor in the development of acute renal failure in diabetic patients with diabetic nephropathy and in patients with combined renal and hepatic disease.

Under the direction of personnel with the prerequisite training and with a thorough knowledge of the pharmacology, use of manifold systems and/or three-way stopcocks, frequent catheter flushing with heparinized saline solutions and monitoring 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.

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Adverse reactions following the use of OMNIPAQUE 140, OMNIPAQUE 240, OMNIPAQUE 300, and OMNIPAQUE 350 generally were less frequent than with adults.

Cardiovascular System: Ventricular tachycardia (0.5%), 2:1 heart block (0.5%), hypertension (0.3%), and anemia (0.3%).

Nervous System: Pain (0.8%), fever (0.5%), taste alteration (0.3%), and convulsion (0.3%).

Respiratory System: Congestion (0.3%) and apnea (0.3%).

Gastrointestinal System: Nausea (1%), hypoglycemia (0.3%), and vomiting (2%).

Skin and Appendages: Urticaria (0.3%), pruritus (0.1%), and pruritus (0.1%).

Individual adverse reactions which occurred to a significantly greater extent for a specific procedure are listed below for that indication.

Pediatrics
In controlled clinical trials involving 191 patients for pediatric angiography, urography, and contrast medium associated complications, adverse reactions following the use of OMNIPAQUE 240, OMNIPAQUE 300, and OMNIPAQUE 350 were generally less frequent than with adults.

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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 incidence of an adverse reaction. Most procedures do not require use of the maximum volume or the highest concentration of OMNIPAQUE. The combination of volume and concentration of OMNIPAQUE to be used will depend carefully on individual circumstances. Signs and symptoms related to the respiratory system: pulmonary or laryngeal edema, bronchospasm, dyspnea, or to the nervous system: convulsion, tremor, faintness, tachycardia, and other allergic reactions should be considered. In controlled clinical trials involving 191 patients for pediatric angiography, urography, and contrast medium associated complications, adverse reactions following the use of OMNIPAQUE 240, OMNIPAQUE 300, and OMNIPAQUE 350 were generally less frequent than with adults.

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Pediatrics: OMNIPAQUE 350 (87.5 g albuminuria, hematuria, and an elevated creatinine and urea nitrogen. Rapid and complete return has been reported in patients with aortoiliac obstruction, femoral artery obstruction, abdominal and retroperitoneal space. Under conditions of slow aortic circulation there is an increased likelihood for aortography to visualization of multiple vascular systems and target organs is possible during a single 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 maximum total volume should not exceed 250 mL (87.5 g). Patients: 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 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. The dosage recommended for use in adults for use in angiography and selective visceral arteriography including studies of the aortic arch, ascending aorta, and abdominal aorta and its branches (celiac, mesenteric, renal, hepatic and splenic arteries). OMNIPAQUE 350 at a concentration of 350 mg I/mL is indicated in children for use in angiography and selective studies of the aortic root, arch, coronary arteries, and visceral branches:.

**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 inotropic heart failure because of the possibility of aggravating the preexisting condition. Hypotension should be corrected promptly since it may induce serious arrhythmias. Special care regarding dosage should be observed in patients with right ventricular failure, pulmonary hypertension, or stenotic pulmonary vascular beds because of the hemodynamic changes which may occur after injection into the right heart 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, as well as the size of the structure to be visualized, the anticipated degree of hemodilution, and vascularity weight. A minor consideration in adults, but should be considered in infants and 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 between injection to allow for the dissipation of possible hemodynamic disturbances.

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

**Pulmonary Angiography**

Patients: 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. Under conditions of slow aortic circulation there is an increased likelihood for aortography to visualize such as photomas of 1-second or less duration. Cerebral arteriography with water-soluble contrast media has been associated with temporary untoward reactions. (See PRECAUTIONS—General.)

Enhancement of computed tomography with OMNIPAQUE may be of benefit in establishing certain diagnoses of certain lesions in these sites with greater assurance than is possible with CT alone. In other cases, the contrast agent may allow visualization of lesions not seen with CT alone. Enhancement or definition may help to define suspicious lesions with unenhanced CT lie, pancreatic cysts. For information regarding the use of iodinated contrast media in CT of the abdomen, see INDIVIDUAL INDICATIONS AND USAGE—Oral Use.

**Precautions**

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

OMNIPAQUE (iohexol) Injection

**Adverse Reactions**

Immediately following intravascular injection of contrast medium, a transient sensation of mild warmth is not unusual. Warmth is less frequent with OMNIPAQUE than with ionic media. (See ADVERSE REACTIONS: Intravascular—General.)

**Dosage and Administration**

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

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

OMNIPAQUE 240 at a concentration of 240 mg I/mL, and OMNIPAQUE 350 at a concentration of 350 mg I/mL is indicated in adults for use in intravenous contrast enhanced computed tomographic head imaging by rapid bolus injection.

**CT SCANNING OF THE BODY**

OMNIPAQUE may be used to redefine diagnostic precision in areas of the brain which may otherwise have been unsatisfactorily visualized.

**Tumors**

OMNIPAQUE may be useful to investigate the presence and extent of certain malignancies such as: gliomas, including malignant gliomas, glioblastomas, astrocytomas, oligodendrogliomas and gangli-gliomas, ependymomas, medulloblastomas and meningiomas, neurofibromas, melanomas, pituitary adenomas, carcinopharyngiomas, germinomas, and metastatic lesions. The usefulness of contrast enhancement for the investigation of the retroperitoneal space and in cases of low grade or infiltrative glomas has not been demonstrated. In calcified lesions, there is less likelihood of enhancement. Following therapy, tumors may show decreased or no enhancement. The opacification of the inferior vermis following 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 infarctions of recent onset may be better visualized with contrast enhancement, while some infarctions are discovered if contrast enhanced CT is used. The use of iodinated contrast media results in enhancement in about 60 percent of cerebral infarctions studied from one to four weeks from the onset of symptoms. Sites of active infection may also be enhanced following contrast medium administration. Arteriovenous malformations and aneurysms will show contrast enhancement. For these vascular lesions the enhancement is probably dependent on the ionic content of the circulating blood pool. Hematomas may be enhanced, while those developed after contrast agent injection are not.

Enhancement of computed tomography with OMNIPAQUE may be of benefit in establishing diagnoses in lesions in the head, neck, pancreas, kidneys, aorta, mediastinum, pelvis, abdominal cavity, and intraperitoneal space.

Cerebral arteriography with water-soluble contrast media may be repeated as necessary. When combined with selective coronary arteriography, the total administered volume should not exceed 250 mL (87.5 g).
peripheral vein, the superior vena cava or right atrium, usually by mechanical injection although sometimes by rapid manual injection. The technique has been used to visualize the vertebrae, aorta and most of its larger branches, including the carotids, cerebels, vertebrals, renal, celiac, mesenter- 
ics, and the peripheral vessels of the limbs. Radiopaque visualization of these structures is possible unless significant hemodilution occurs.

OMNIPAQUE 350 can be injected intra-arterially as a rapid bolus to provide arterial visualization using digital subtraction radiography. Preprocedural medications are not considered necessary. OMNIPAQUE 350 has provided diagnostic arterial radiographs in about 95% of patients. In some cases, poor arterial visualization has been attributed to patient movement. OMNIPAQUE 350 is very well tolerated in the vascular system. Patient discomfort (general sensation of heat and/or pain) following injection is less than with various other contrast media.

Precautions
Since the contrast medium is usually administered mechanically under high pressure, rupture of smaller peripheral veins can occur. It has been suggested that this can be avoided by using an intra-arterial catheter threaded preferentially beyond larger tributaries or, in the case of the antecubital vein, into the superior vena cava. Sometimes the femoral vein is used. (See PRECAUTIONS—General.)

Adverse Reactions
Cardiovascular system reactions in digital angiography included transient PACs (16%) and PACs (6.5%). (See ADVERSE REACTIONS: Intravascular—General.)

Dosage and Administration
The usual injection volume of OMNIPAQUE 350 for the intravenous technique is 30 mL to 50 mL of a 350 mg/mL solution. This is administered as a bolus at 7.5 to 30 mL/second using a pressure injector. The volume and rate of injection will depend primarily on the type of equipment and technique used.

Intra-arterial Administration
OMNIPAQUE 140 at a concentration of 140 mg/mL is indicated for use in intra-arterial digital subtraction angiography of 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 hemodilution 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.)

INDICATIONS AND USAGE—General
OMNIPAQUE 300 is indicated for examination of the gastrointestinal tract. OMNIPAQUE 180 is indicated in children for examination of the gastrointestinal tract. OMNIPAQUE 240 is indicated in adults for arthrography, endoscopic retrograde pancreatography and cholangiopancreatography, hysterosalpingography, and hysteroscopy.

PERIPHERAL ANGIOGRAPHY
OMNIPAQUE 300 at a concentration of 300 mg/mL or OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in peripheral arteriography. OMNIPAQUE 240 at a concentration of 240 mg/mL or OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in adults for use in peripheral venography.

Adverse Reactions
Central nervous system reactions in intra-arterial digital angiography include transient ischemia attacks (1.6%) and cerebral infections (1.6%). These occurred in high risk patients having a cerebral examination and the relationship to the contrast medium was unaltered. (See ADVERSE REACTIONS: General—General)

Pulmonary
Pulmonary reactions are usually mild and occur more frequently in patients undergoing pulmonary angiography or bronchography. Pulmonary reactions include cough, shortness of breath, chest pain, dyspnea, hypotension, and hemoptysis. These reactions are more frequent in patients with pre-existing lung disease. Pulmonary reactions are not associated with the use of OMNIPAQUE 140.

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: Intravascular—General.)

Dosage and Administration
The volume required will depend on the size, flow rate, and disease state of the injected vessel and on the size, flow rate, and disease state of the vessel to be visualized. The dosage recommended for use in peripheral angiography is as follows:

Arteries
Volume/Injection Rate of Injection
(mL) (mL/sec)
Aorta
20-45
8-20
Carotid
5-10
3-6
Femoral
9-20
3-6
Vertebral
6-10
2-8
Renal
6-12
2-8
Other Branches of the Aorta
8-25
3-10
Includes subclavian, axillary, innominate and iliac

Venuography
(mL)
Volume/Injection Rate of Injection
20 mL to 30 mL of OMNIPAQUE 350 (350 mg/mL)
40 mL to 100 mL of OMNIPAQUE 350 (300 mg/mL)

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.

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

WARNINGS—General
Orally administered iohexol is very poorly absorbed from the normal gastrointestinal tract. Only 0.1% of the oral dose is absorbed by the kidneys and bowel as previously described in SECTION II, CLINICAL PHARMACOLOGY—Intravascular.

ADVERSE REACTIONS: Oral/Body Cavity Use
For most body cavities, the injected iohexol 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 lavage cystourethrography involve the almost immediate drainage of contrast medium from the cavity upon conclusion of the radiographic procedure.

OMNIPAQUE 300 is very slowly absorbed from the normal gastrointestinal tract. Only 0.1% of the oral dose was excreted by the kidneys. This amount may increase in the presence of bowel perforation or bowel obstruction. iohexol is well tolerated and readily absorbed if leakage into the peritoneal cavity occurs.

Ultrasound leakage into the peritoneal cavity occurs. OMNIPAQUE 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
OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in adults for use in excretory urography. OMNIPAQUE 350 at a concentration of 350 mg/mL is indicated in adults for use in renal arteriography and in children for use in renal arteriography and renal venography.

PRECAUTIONS—General
Orally administered iohexol may cause diarrhea and abdominal pain. Patients taking iohexol should be instructed to report any unusual abdominal pain. Oral administration of iohexol may be associated with flushing.

ADVERSE REACTIONS: Oral/Body 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.

Adverse Reactions
Inhalation
Incidence > 1%: None
Incidence < 1%: None

Gastrointestinal
Incidence > 1%: None
Incidence < 1%: None

Skin
Incidence > 1%: None
Incidence < 1%: None

Others
Incidence > 1%: None
Incidence < 1%: None

No adverse reactions associated with the use of OMNIPAQUE for VCU procedures were reported in 51 pediatric patients studied.

Oral Use
See INDIVIDUAL INDICATIONS AND USAGE—Oral Use—Adverse Reactions.
OVERDOSAGE

See also SECTION II, OVERDOSAGE.
The recommended dose of OMNIPAQUE 350 at a concentration of 350 mgI/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 adverse reactions was 91% (10 of 11) and included abdominal cramping and diarrhea 27% (3 of 11). Despite all of these events being mild and transient, the adverse reaction frequencies were more than double that seen in the recommendation. It is apparent from this finding that larger volumes of hypotonic contrast media, like OMNIPAQUE, increase the osmotic load and the risk of fluid shift which may result in precipitation.

DOSAGE AND ADMINISTRATION—General

INDIVIDUAL INDICATIONS AND USAGE

Oral Use

Adults: OMNIPAQUE 350 at a concentration of 350 mgI/mL is indicated in adults for use in oral pass-
thru examination of the gastrointestinal tract.

OMNIPAQUE diluted to concentrations from 6 mgI/mL to 9 mgI/mL, administered orally or rectally is indicated in children for use in examination of the gastrointestinal tract.

OMNIPAQUE 240 at a concentration of 240 mgI/mL administered orally or rectally is indicated in children for use in examination of the gastrointestinal tract.

OMNIPAQUE diluted to concentrations from 9 mgI/mL to 21 mgI/mL administered orally or rectally in conjunction with OMNIPAQUE 240 at a concentration of 240 mgI/mL or OMNIPAQUE 300 at a concentration of 300 mgI/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 abdominal cramping have also been reported following oral administration of 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 intravenous component of the solution. It should be noted that serious or anaphylactoid reactions that may occur with intravascular administration are possible following administration by any route.

Adverse Reactions

In controlled clinical trials involving 54 adult patients for oral pass-thru examination of the gastrointestinal tract using OMNIPAQUE 350, the following adverse reactions were reported: diarrhea (36%), vomiting (9%), nausea (5%), fever (5%), hypotension (2%), abdominal pain (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 300, adverse reactions were limited to a single report of vomiting (2%).

In controlled clinical studies involving 58 pediatric patients for examination of the gastrointestinal tract at concentrations of 180 and 300 mgI/mL, the following adverse reactions were reported: diarrhea (36%), vomiting (19%), nausea (15%), fever (15%), hypotension (2%), abdominal pain (2%), and headache (2%). In clinical studies an increased frequency and severity of diarrhea was reported: diarrhea (36%), vomiting (9%), nausea (5%), fever (5%), hypotension (2%), abdominal pain (2%), and headache (2%).

In controlled clinical studies involving 69 pediatric patients for dilute oral plus intravenous CT examination of the gastrointestinal tract using OMNIPAQUE 300, adverse reactions were limited to a single report of vomiting (2%).

Dosage and Administration

Administered volumes are indicated in adult patients for use in oral pass-thru examination of the gastrointestinal tract.

OMNIPAQUE 180 at a concentration of 180 mgI/mL administered orally or rectally is indicated in children from 3 months to 18 years of age. The oral dosage may be given about 30 to 60 minutes prior to the intravenous dose and image acquisition.

In clinical studies an increased frequency and severity of diarrhea was reported: diarrhea (36%), vomiting (9%), nausea (5%), fever (5%), hypotension (2%), abdominal pain (2%), and headache (2%).

OMNIPAQUE 240 at a concentration of 240 mgI/mL administered orally or rectally is indicated in children from use in examination of the gastrointestinal tract.

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

Precautions

See PRECAUTIONS—General.

Adverse Reactions

OMNIPAQUE may be diluted, utilizing asceptic technique, with Sterile Water for Injection to a concentra-
tion of 1 mgI/mL for voiding cystourethrography. The concentration of the final solution may vary, dependent upon the patient’s size and age and also with the technique and equipment used. Sufficient volume of the contrast medium should be administered to adequately fill the bladder. The usual volume ranges from 50 mL to 300 mL of OMNIPAQUE at a concentration of 100 mgI/mL and 50 mL to 600 mL of OMNIPAQUE at a concentration of 50 mgI/mL.

OMNIPAQUE may be diluted with Sterile Water for Injection as indicated in the table below:

| To Achieve | Add To | Each 100 mL of OMNIPAQUE
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Concentration</td>
<td>Sterile Water for Injection, USP (mL)</td>
<td></td>
</tr>
<tr>
<td>Image</td>
<td>OMNIPAQUE 240</td>
<td>OMNIPAQUE 300</td>
</tr>
<tr>
<td>100</td>
<td>140</td>
<td>200</td>
</tr>
<tr>
<td>90</td>
<td>167</td>
<td>233</td>
</tr>
<tr>
<td>80</td>
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Dilutions of OMNIPAQUE should be prepared just prior to use and any unused portion discarded after the procedure.

VOIDING CYSTOURETHROGRAPHY (VCU)

OMNIPAQUE diluted to concentrations from 50 mgI/mL to 100 mgI/mL is indicated in children for voiding cystourethrography. VUCs are often performed in conjunction with excretory urography.

Precautions

Since the VCU procedure requires instrumentation, special precautions should be observed in those patients known to have an acute urinary tract infection. Filling of the bladder should be done at a steady rate, exercising caution to avoid excessive pressure. Sterile procedures are essential.

Adverse Reactions

OMNIPAQUE may be diluted, utilizing asceptic technique, with Sterile Water for Injection to a concentra-
tion of 1 mgI/mL for voiding cystourethrography. The concentration of the final solution may vary, dependent upon the patient’s size and age and also with the technique and equipment used. Sufficient volume of the contrast medium should be administered to adequately fill the bladder. The usual volume ranges from 50 mL to 300 mL of OMNIPAQUE at a concentration of 100 mgI/mL and 50 mL to 600 mL of OMNIPAQUE at a concentration of 50 mgI/mL.

OMNIPAQUE may be diluted with Sterile Water for Injection as indicated in the table below:

| To Achieve | Add To | Each 100 mL of OMNIPAQUE
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<tbody>
<tr>
<td>Concentration</td>
<td>Sterile Water for Injection, USP (mL)</td>
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<tr>
<td>Image</td>
<td>OMNIPAQUE 240</td>
<td>OMNIPAQUE 300</td>
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<tr>
<td>100</td>
<td>140</td>
<td>200</td>
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<td>90</td>
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Dilutions of OMNIPAQUE should be prepared just prior to use and any unused portion discarded after the procedure.

ARTHROGRAPHY

OMNIPAQUE 240 at a concentration of 240 mgI/mL or OMNIPAQUE 300 at a concentration of 300 mgI/mL or OMNIPAQUE 350 at a concentration of 350 mgI/mL is indicated in radiography of the knee joint in adults, and OMNIPAQUE 240 at a concentration of 240 mgI/mL or OMNIPAQUE 300 at a concentration of 300 mgI/mL is indicated in radiography of the shoulder joint in adults, and OMNIPAQUE 300 at a concentration of 300 mgI/mL is indicated in radiography of the temporomandibular joint in adults. Arthrography may be helpful in the diagnosis of diarthromorphic or degenerative joint diseases, synovial rupture, the visualization of communicating bursae or cysts, and in meniscography.

Precautions

See PRECAUTIONS—General.

Strict aseptic technique is required to prevent infection. Fluoroscopic control should be used to ensure proper needle placement, prevent extravascular injection, and prevent dilation of contrast medium. Undue pressure should not be exerted during injection.

Adverse Reactions

Injection of OMNIPAQUE into the joint is associated with transient discomfort, ie, pain, swelling. However, delayed, severe or persistent discomfort may occur occasionally. Severe pain may often result from undue use of pressure or the injection of large volumes. Joint swelling after injection is less with OMNIPAQUE than with high osmolar ionic contrast medium. These types of reactions are generally procedurally dependent and of greater frequency when double-contrast technique is employed.

Nervous system: Swelling sensation (42%), pain (29%), heat sensation (13%), and muscle weakness (12%).

Skin and appendages: Hematoma at injection site (0.7%).

Dosage and Administration

Arthrography is usually performed under local anesthesia. The amount of OMNIPAQUE injected is dependent on the size of the joint to be examined and the technique employed. Lower volumes of contrast medium are usually injected for knee and shoulder arthrography when double-contrast examinations using 15 mL to 100 mL of air are performed.

The following concentrations and volumes are recommended for normal adult knee, shoulder, and temporomandibular joints but should serve as guidelines since joints may require more or less contrast medium for optimal visualization.

KNEE

OMNIPAQUE 350 5 mL to 15 mL
OMNIPAQUE 300 5 mL to 10 mL
OMNIPAQUE 240 3 mL

SHOULDER

OMNIPAQUE 350 10 mL
OMNIPAQUE 240 3 mL

TEMPOROMANDIBULAR

OMNIPAQUE 300 0.5 mL to 1.0 mL
OMNIPAQUE (iohexol) Injection

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

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

Precautions
See PRECAUTIONS—General.

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 as much to the procedure itself as 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: Pain (17%), somnolence (1%), and burning (1%).

Gastrointestinal system: Vomiting, diarrhea, and pressure, each with an individual incidence of 1%.

Doseage and Administration
The recommended dose of OMNIPAQUE 240 at a concentration of 240 mg/I 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/I or OMNIPAQUE 300 at a concentration of 300 mg/I 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 should be 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. The cause of the pain may be due as much to the procedure itself as to the contrast medium injected, therefore attention should be paid to the injection pressure and volume instilled to avoid disruptive distention of the uterus and fallopian tubes. Fluoroscopic monitoring is recommended.

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

Gastrointestinal system: Nausea (3%).

Doseage 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 will vary depending on individual anatomy and/or disease state.

HERNIOGRAPHY

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

Precautions
See PRECAUTIONS—General.

Adverse Reactions
Nervous system: Pain (7%), headache (3%), and unwell feeling (3%).

Gastrointestinal system: Diarrhea (3%) and flatulence (10%).

Doseage 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 140
50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1401-52)

OMNIPAQUE 180
10 mL glass vial, 180 mg/I/mL, boxes of 10 (NDC 0407-1411-10)
20 mL glass vial, 180 mg/I/mL, boxes of 10 (NDC 0407-1411-20)

OMNIPAQUE 240
10 mL glass vial, 240 mg/I/mL, boxes of 10 (NDC 0407-1412-10)
20 mL glass vial, 240 mg/I/mL, boxes of 10 (NDC 0407-1412-20)

OMNIPAQUE 300
10 mL glass vial, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-10)
30 mL glass vial, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-30)
30 mL fill in 50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-59)
50 mL glass vial, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-30)
50 mL glass vial, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-51)
50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-61)
75 mL fill in 100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-62)
100 mL glass bottle, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-60)
100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-63)
125 mL fill in 150 mL glass bottle, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-53)
150 mL glass bottle, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-90)
150 mL fill in 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-65)
200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-66)

OMNIPAQUE 350
50 mL glass vial, 350 mg/I/mL, boxes of 10 (NDC 0407-1414-50)
50 mL glass bottle, 350 mg/I/mL, boxes of 10 (NDC 0407-1414-51)
50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-89)
75 mL fill in 100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-90)
100 mL glass bottle, 350 mg/I/mL, boxes of 10 (NDC 0407-1414-60)
100 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-91)
125 mL fill in 150 mL glass bottle, 350 mg/I/mL, boxes of 10 (NDC 0407-1414-76)
150 mL glass bottle, 350 mg/I/mL, boxes of 10 (NDC 0407-1414-03)

150 mL fill in 200 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-93)
200 mL fill in 250 mL bottle with hanger, 350 mg/I/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/I/mL, boxes of 10 (NDC 0407-1414-80)

FEDERAL GOVERNMENT CODES

OMNIPAQUE 240
50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1412-29)
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/I/mL, boxes of 10 (NDC 0407-1413-11)
50 mL glass bottle, 300 mg/I/mL, boxes of 10 (NDC 0407-1413-93)
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/I/mL, boxes of 10 (NDC 0407-1414-52)
10 mL glass vial, 350 mg/I/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]. OMNIPAQUE injection in all presentations may be stored in a contrast media warmer for up to one month at 37°C (98.6°F).

SPECIAL HANDLING AND STORAGE FOR POLYMER BOTTLES ONLY: DO NOT USE IF TAMPER-EVIDENT RING IS BROKEN OR MISSING.

Revised May 2010