+PLUSPAK packaging offers additional advantages

- Compact design means less storage space required
- Lightweight, pharmaceutical grade polypropylene packaging allows for lower disposal costs

For more information, visit www.pluspak.com

References:

Next to glass, +PLUSPAK™ packaging is just plain safer.

+PLUSPAK™ packaging aids regulatory compliance

- Adheres to both Joint Commission and OSHA Compliance Standards
- Proper labeling and communication are critical when transferring contrast media from one container to another
- Reducing worker exposure to occupational hazards is a priority (OSHA)
- Reducing exposure to occupational hazards is a priority (Joint Commission)
- Increased tracking of other containers
- Compliance with Joint Commission standards
- Peel-off tracking labels allow for:
  - Compliance with Joint Commission standards
  - Accurate labeling of other containers
  - Easy product documentation
  - Latex-free stopper eliminates risk of latex allergy
  - Lightweight design and twist-off cap allows for safer, ergonomic handling
+PLUSPAK packaging reduces risk of sharps injuries

- Along with common sharps injuries such as needlesticks, healthcare workers also can be injured by the broken metal crimps of glass packaging.
- Sharps injuries remain the leading occupational hazard for healthcare workers.
- Sharps injuries are the source of nearly 66,000 hepatitis B, 16,000 hepatitis C, and 200–5,000 HIV cases worldwide.

+PLUSPAK packaging is GE Healthcare’s innovative solution to cuts and contamination associated with glass packaging

- Metal-free, twist-off cap avoids cuts from metal crimps
- Unbreakable polypropylene eliminates glass breakage
+PLUSPAK packaging offers additional advantages

- Compact design means less storage space required
- Lightweight, pharmaceutical grade polypropylene packaging allows for lower disposal costs

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References:

+PLUSPAK™ packaging aids regulatory compliance

Both the Joint Commission and Occupational Safety and Health Administration (OSHA) guidelines are clear:
- Proper labeling and communication are critical when transferring contrast media from one container to another (Joint Commission, National Patient Safety Goals)
- Reducing worker exposure to occupational hazards is a priority (OSHA)
- Healthcare facilities are required to take advantage of available safety devices (Joint Commission)

+PLUSPAK packaging adheres to both Joint Commission and OSHA Compliance Standards

- Peel-off tracking labels allow for:
  - Compliance with Joint Commission standards
  - Accurate labeling of other containers
  - Compliant with Joint Commission standards
- Latex-free stopper eliminates risk of latex allergy
- Lightweight design and twist-off cap allow for safer, ergonomic handling

+PLUSPAK™ (polymer bottle)
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—CONTRAINDICATIONS TO 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 major motor seizures, cerebral vasospasm, intracranial arterial spasm, cerebral infarction, hyperthermia, drug fever, 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 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 technique used.

Parenteral products should be maintained on this therapy. Should a severe intravenous diazepam or phenobarbital sodium is recommended. In patients with a history of seizure activity who are not on anticonvulsant therapy, premedication with barbiturates should be considered.

Prophylactic 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 antiemetic and antiarhythmia properties, are not recommended for use with OMNIpaque. Other drugs include MAO inhibitors, tricyclic antidepressants, CNS stimulants, and psychoactive drugs described as antimuscarinic, major tranquillizers, or antipsychotic drugs. 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. Physicians have discontinued these agents at least 48 hours before and for at least 48 hours postmyelography.

Core 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 medium causing inadvertent rise to intracranial levels (eg, by active patient movement). Direct concentrated bolus of the medium. Also, effort should be directed to avoid rapid dispersion of the medium causing inadvertent rise to intracranial levels (eg, by active patient movement). Direct intracranial or ventricular administration for standard radiography (not CT) is not recommended. In most reported cases of major motor seizures with nonionic myelographic media, one or more of the following factors were present. Therefore avoid:

- Deviations from recommended procedure or in myelographic management.
- Use in patients with a history of epilepsy.
- Overdose
- Intrathecal entry of a bolus or premature diffusion of a high concentration of the medium.
- Medication with neuroleptic drugs or phenothiazine antipsychotics.
- Failure to maintain elevation of the head during the procedure, on the stretcher, or in bed.
- Excessive and particularly active patient movement or straining.

PRECAUTIONS—General

Diagnostic procedures which involve the use of radiopaque diagnostic agents should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed. Appropriate facilities should be available for coping with any complication of the procedure, as well as for emergency treatment of severe reactions to the contrast agent itself. After parenteral administration of a radiopaque agent, competent personnel and emergency facilities should be available for at least 30 to 60 minutes since severe delayed reactions have occurred. (See ADVERSE REACTIONS.)

Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with serious cardiovascular disease). Oral hydration in these patients should be enhanced by the osmotic diuretic action of contrast agents. Patients should be well hydrated prior to and following administration of any contrast medium, including iohexol.

The possibility of a reaction, including serious, life-threatening, fatal, anaphylactic, cardiovascular or central nervous system reactions, should always be considered (see ADVERSE REACTIONS). Therefore, the use of extreme caution is indicated prior to administration of the drug. The possibility 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 for 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 to avoid or minimize possible allergic reactions in such patients should be considered. Recent reports indicate that some premedication does not prevent serious life-threatening reactions, but may reduce both their incidence and severity.

In patients with severe renal insufficiency or failure, compensatory biliary excretion of the drug is anticipated to occur, with a slow clearance into the bile. Patients with hepatic 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 noncompressible equipment is used, scrupulous care 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 are seen, the solution should not be used.

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 (see DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY).

Information for Patients (or if applicable, children)

Patients receiving intrathecal radiopaque diagnostic agents should be instructed to:

- Inform your physician if you are pregnant (see CLINICAL PHARMACOLOGY).
The most frequently occurring adverse reaction following myelography has been headache. To avoid excessive mixing with CSF and consequent dilution of contrast, injection should be slow. Transient dizziness was reported in about 2% of the patients. 1.3% of patients developed nausea and vomiting. Nausea was more common in children than in adults. These reactions usually occur 1 to 10 hours after injection, and almost all occur within 24 hours. They are usually mild to moderate in degree, lasting for a few hours, and usually disappearing within 24 hours. Rarely, headaches developed severe enough to require hospitalization. Headaches on 180 mg/mL OMNIPAQUE and vomiting tend 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. These reactions reported in clinical studies with OMNIPAQUE are listed below in decreasing order of occurrence, based on clinical studies of 1531 patients.

ADVERSE REACTIONS—Intrathecal

The most frequently reported adverse reactions with OMNIPAQUE are headache, mild to moderate pain, and dizziness. Headaches may occur with all concentrations of OMNIPAQUE and are related to the control of nausea or vomiting during or after myelography, and should not be resumed for at least 24 hours postprocedure. In noneffective procedures in patients on these drugs, consider prophylactic use of antihistamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category

Reproduction studies have been performed in rats and rabbits with up to 100 times the recom- mended human dose. No evidence of impaired fertility or harm to the fetus has been demonstrated due to OMNIPAQUE. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction 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. Breast feeding may be substituted for breast feeding for 24 hours following administration of OMNIPAQUE.

Pediatric Use

Pediatric patients at higher risk of experiencing adverse events during contrast medium administra- tion 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.

PROCEDURE FORMULATIONS

The volume and concentration of OMNIPAQUE 180, OMNIPAQUE 240, or OMNIPAQUE 300 to be used will depend on the department of radiology, the patient’s size, age, and condition, the local and national guidelines used by the radiology department, and the diagnostic procedure to be performed. The volume and concentration of OMNIPAQUE 180, OMNIPAQUE 240, or OMNIPAQUE 300 to be used will depend on the estimated volume of contrast medium which may be required for the procedure. 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 cerebral puncture needle may be removed immediately following injection since it is not necessary to remove OMNIPAQUE after injection into the subarachnoid space.

Pediatrics: The usual recommended total doses for lumbar, thoracic, and cervical, and total columnar myelography in children are 1.2 g to 3.06 g as follows:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Formulations</th>
<th>Concentration (mg/mL)</th>
<th>Volume (mL)</th>
<th>Dose (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>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 240</td>
<td>240</td>
<td>7-12.5</td>
</tr>
<tr>
<td>Thoracic</td>
<td>Myelography</td>
<td>OMNIPAQUE 240</td>
<td>240</td>
<td>6-12.5</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
</tr>
<tr>
<td>Cervical</td>
<td>Myelography</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
<td>7-10</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 240</td>
<td>240</td>
<td>6-12.5</td>
</tr>
<tr>
<td>Cervical</td>
<td>Myelography</td>
<td>OMNIPAQUE 300</td>
<td>300</td>
<td>6-10</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
<td>7-10</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 240</td>
<td>240</td>
<td>6-12.5</td>
</tr>
<tr>
<td>Total Columnar Myelography</td>
<td>OMNIPAQUE 180</td>
<td>180</td>
<td>7-10</td>
<td>1.3-1.8</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</td>
<td>OMNIPAQUE 240</td>
<td>240</td>
<td>6-12.5</td>
</tr>
<tr>
<td>L2-L4</td>
<td>i/o lumbar</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>Total Columnar Myelography</th>
<th>Concentration (mg/mL)</th>
<th>Volume (mL)</th>
<th>Dose (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to &lt; 3 mos.</td>
<td>0.5-0.72</td>
<td>6-12</td>
<td>0.27-1.44</td>
</tr>
<tr>
<td>3 to &lt; 36 mos.</td>
<td>8-10</td>
<td>3-12</td>
<td>0.9-1.8</td>
</tr>
<tr>
<td>3 to 7 yrs.</td>
<td>10-12</td>
<td>3-12</td>
<td>0.9-1.8</td>
</tr>
<tr>
<td>7 to 12 yrs.</td>
<td>12-15</td>
<td>3-12</td>
<td>0.9-1.8</td>
</tr>
<tr>
<td>13 to 18 yrs.</td>
<td>15-18</td>
<td>3-12</td>
<td>0.9-1.8</td>
</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: The usual recommended total dose for intravenous injection has been reported. It is generally recommended for intravenous injection or for rapid dilution prior to administration. If particulate matter or discoloration is present, do not use.

Repeat Procedures: If 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. An interval of at least 48 hours should be allowed before repeat examination; however, whenever possible, 5 to 7 days is recommended.
and only as necessary.

I

or other nonvascular lesion. The pharmacokinetics of iohexol in both normal and abnormal tissue have been shown to be exponential. compartments which causes an initial sharp fall in plasma concentration. Equilibration with the extent following intravascular administration.

what extent iohexol is excreted in human milk. In infants with immature kidneys, the route of excretion through the gallbladder and into the small impairment, prolonged plasma iohexol levels may be anticipated. In these patients, as well as in those with severe renal impairment may result unpredictably, and opacification may be delayed after injection. Severe renal impairment may result about 1 to 3 minutes with optimal contrast occurring between 5 to 15 minutes. In nephropathic

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 urinary iohexol levels indicate that the iohexol body clearance is due primarily to renal clearance. An increase in the dose from 500 mg iodine/kg to 1500 mg iodine/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 iodine/kg to 1500 mg iodine/kg to 16 adult human subjects: renal clearance—120 (98-166) mL/min; total body clearance—131 (98-165) mL/min; and volume of distribution—165 (108-219) mL/kg.

Contrast enhancement in tissue frequently occurs after peak blood iodine levels are reached or after intravascular administration. Maximum enhanced images of the brain have been obtained up to 1 hour after intravenous bolus administration. This delay is consistent with the radiographic enhancement in contrast medium which is 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 nonvascular lesions is not as reproducible as that of 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 contrast medium should be assessed on an individual risk to benefit basis. However, compared to ionic media, nonionic media are less toxic to the central nervous system.

INDICATIONS AND USAGE, GENERAL—Intravascular

OMNIPAQUE 350 is indicated in children for angiocardiography (angiography), pulmonary arteriography, and venography; studies of the collateral arteries and aortography, including the aorta, aortic arch, ascending and descending aorta.

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 and excretory urography.

OMNIPAQUE 300 is indicated in children for angiocardiography (angiography), 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.

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

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

WARNINGs—General

Nonglucuronated contrast media, when injected into blood vessels, are less reactive than ionic contrast media. Clotting has not been reported when blood remains in contact with syringes containing nonionic contrast media. Serum sickness, 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 include close attention to guidance catheter and manipulation, use of manifold systems and/or three-way stopcocks, frequent flushing with heparin 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, as well as in those with liver disease of less severe degree, such as alcoholic liver disease. Blood serum bilirubin levels 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 anemia. Radiopaque contrast media, when injected intravenously, may promote sickling in individuals who are homozygous for sickle cell disease.

The risk in nonhematopoietic tissues patients is not a contraindication; however, special precautions are necessary. Partial dehydrogenation in the presence of these patients. When this potential reaction is not recommended since this may predispose the patient to precipitation of the myeloma protein in the renal tubules. No form of therapy, including diafiltration and peritoneal dialysis, has been shown to be effective in patients with multiple myeloma. The risk in dialysis patients over age 40, should be considered before instituting intravascular administration of contrast agents.

Intravascular contrast media, when injected intravenously or intra-arterially, may promote sickling in individuals who are homozygous for sickle cell disease.

Administration of radiopaque materials to patients known or suspected of having phaeochromocytoma should be performed with extreme caution. If, in the opinion of the physician, the possible benefit of such procedures outweigh the considered risks, the procedures may be performed; however, the administration of radiopaque media to patients with multiple myeloma may be contraindicated. Patients should be well hydrated prior to and following administration of any contrast medium. Patients with preexisting renal disease, infants and small children. Dehydration in these patients seems to be enhanced by the osmotic diuretic action of urographic agents. It is believed that overnight fluid replacement therapy is necessary in certain patients with diabetes mellitus. In normal patients. Patients should be well hydrated prior to and following administration of any contrast medium, including iohexol. Acute renal failure has been reported in diabetic patients with diabetic nephropathy and in susceptible non-diabetic patients often elderly with preexisting renal disease second severe delayed Preparations have been reported to cause acute renal failure in patients with diabetic nephropathy and in susceptible non-diabetic patients in susceptible non-diabetic patients. Acute renal failure has been reported in diabetic patients with diabetic nephropathy and in susceptible non-diabetic patients often elderly with preexisting renal disease second severe delayed Preparations have been reported to cause acute renal failure in patients with diabetic nephropathy and in susceptible non-diabetic patients.
Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Chemotoxic reactions result from the physicochemical properties of the contrast media, the dose, and speed of injection. All hemodynamic disturbances and injuries to organs or vessels perfused by the contrast media are included in this category. Idiosyncratic reactions include all other reactions as long as they are not chemotoxic reactions. They occur more frequently in patients 20 to 40 years old. Idiosyncratic reactions may or may not be dependent on the amount of dose injected, the speed of injection, and the medical condition of the patient. If injection of a chemotoxic contrast media results in death, the reaction is accepted as a chemotoxic reaction. If the death is not preceded by cardiovascular collapse, the reaction is accepted as an idiosyncratic reaction. The general death rate is calculated as 0.5 out of 100,000 patients (0.00066 percent) to 1 in 10,000 (0.01 percent). Most deaths occur during injection or 5 to 10 minutes later. Reasons for death can be found in each of the four groups: cardiovascular origin, respiratory origin, other causes, and undetermined cause. The most aggravating factor: isolated reports of hypotensive collapse and shock are found in the literature. The incidence of death is estimated to be 1 percent.

In general, the reactions which are known to occur upon parenteral administration of iodinated contrast media are those due to a foreign protein. If the patient has a history of allergy with a history of allergy with a history of allergy, prior to the injection of any contrast media, may be more accurate than pretesting in predicting potential adverse reactions. The occurrence of severe idiosyncratic reactions has prompted the use of several pretesting procedures. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination.

Inform your physician if you are allergic to any drugs, food, or if you had any reactions to previous injections of dyes used for x-ray procedures (see PRECAUTIONS—General).

Inform your physician about any other medications you are currently taking, including nonprescription drugs, before you are administered this drug.

3. Inform your physician if you are allergic to any drugs, food, or if you had any reactions to previous injections of dyes used for x-ray procedures (see PRECAUTIONS—General).

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Intravascular—General

Adverse reactions to contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Hemodynamic reactions: vein cramp and thrombolysis following intravenous injection. Cardiovascular reactions: rare cases of cardiac arrhythmias, reflex tachycardia, chest pain, cyanosis, hypertension, hypotension, peripheral vasodilation, shock, and cardiac arrest. Renal reactions: occasionally, transient proteinuria, and rarely, oliguria or anuria. Allergic reactions: asthmatic attacks, nasal and conjunctival symptoms, dermal reactions such as urticaria with or without pruritus, as well as pleomorphic rashes, sneezing and lacrimation and, rarely, anaphylactic reactions. Rare fatalities: cardiovascular collapse and death. reunion with traces of cleansing agents.

If iodine-containing isotopes are to be administered for the diagnosis of thyroid disease, the iodine-containing contrast medium should be given at least 10 days after the last administration of radioiodine or other iodine-containing substances. If the patient is allergic to iodine, a contrast medium with no iodine should be administered. Pretesting in predicting potential adverse reactions.

The occurrence of severe idiosyncratic reactions has prompted the use of several pretesting procedures. If nondisposable equipment is used, scrupulous care 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.

Information for Patients

Patients receiving intravenous radiopaque diagnostic agents should be instructed to:

1. Inform your physician if you are pregnant (see CLINICAL PHARMACOLOGY—Intravascular).

2. Inform your physician if you have a history of a sensitivity to medication and/or allergens, congestive heart failure, pulmonary and cardiovascular systems. The symptoms include: cyanosis, bradycardia, acidosis, pulmonary or laryngeal edema, bronchospasm, dyspnea; to the nervous system: restlessness, tremors, convulsions. Other reactions: flushing, pain, warmth, metallic taste, nausea, vomiting, shivering, pallor, weakness of the upper extremities, perioral tingling, and rare, transient proteinuria, and rarely, oliguria or anuria.

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Drug/Laboratory Test Interaction

If iodine-containing isotopes are to be administered for the diagnosis of thyroid disease, the iodine-binding capacity of thyroid tissue may be reduced for up to 7 weeks after contrast medium administration. Thyroid function tests which do not depend on iodine estimation, eg, T3, T4, and TSH, are not affected.

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Drug/Laboratory Test Interaction

If iodine-containing isotopes are to be administered for the diagnosis of thyroid disease, the iodine-binding capacity of thyroid tissue may be reduced for up to 7 weeks after contrast medium administration. Thyroid function tests which do not depend on iodine estimation, eg, T3, T4, and TSH, are not affected.
CEREBRAL ARTERIOGRAPHY

OMNIPAQUE 300 at a concentration of 300 mg/mL is indicated in adults for use in cerebral arteriography.

The degree of pain and flushing as the result of the use of OMNIPAQUE 300 in cerebral arteriography is less than that seen with comparable injections of many contrast media.

In cerebral arteriography, patients should be appropriately prepared consistent with existing or suspected disease states.

Precautions

Cerebral arteriography should be undertaken with extreme care with special caution in elderly patients, patients in poor clinical condition, advanced arteriosclerosis, severe arterial hypertention, recent cerebral embolism or thrombosis, and cardiac decompensation. Since the contrast medium is given by rapid injection, the patient should be monitored for possible untoward reactions. (See PRECAUTIONS—General.)

Adverse Reactions

Cerebral arteriography with water-soluble contrast media has been associated with temporary neurologic complications including seizures, drowsiness, transient paresis, and mild disturbances in vision such as photomas of 1-second or less duration.

Central nervous system side effects in cerebral arteriography included photomas (15%), headache (5.5%), and pain (4.5%). (See ADVERSE REACTIONS: Intravascular—General.)

Dosage and Administration

OMNIPAQUE 300 is recommended for cerebral arteriography at the following volumes: common carotid artery (6 mL to 12 mL), internal 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 intravenous 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 intravenous 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, gliosarcoma, astrocytomas, oligodendrogliomas and gangliogliomas, medulloblastomas, meningiomas, neuremas, aneurysm, pituitary adenomas, carcinopharyngiomas, germinomas, and metastatic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and in cases of low grade or infiltrative gliomas has not been demonstrated. In clinical practice, 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 infarction of recent onset may be better visualized with contrast enhancement, while some infarctions are obscured if contrast medium is used. The use of iodinated contrast media results in enhancement of 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 those vascular lesions the enhancement is probably dependent on the iodine content of the circulating blood pool. Hematomas and intraparenchymal bleeders seldom demonstrate contrast enhancement. However, in cases of intraparenchymal clot, for which there is no obvious clinical explanation, contrast media administration may be helpful in ruling out the possibility of associated arterovenous malformation.

CT SCANNING OF THE BODY

OMNIPAQUE may be useful for enhancement of computed tomographic images for detection and evaluation of lesions in the liver, pancreas, kidneys, aorta, mediastinum, pelvis, abdominal cavity, and retroperitoneal space.

Enhancement of computed tomographic imaging may be of benefit in establishing diagnoses of certain lesions in these sites with greater assurance than is possible with CT alone. In other cases, the contrast agent may enhance visualization of lesions not seen with CT alone (i.e., tumor extension) or may help to define suspicious lesions seen with unenhanced CT, i.e., pancreatic cyst. For information regarding the use of dilute oral plus intravenous OMNIPAQUE in CT of the abdomen, see ADVERSE REACTIONS INDICATIONS AND USAGE—Oral Use.

Precautions

See PRECAUTIONS—General.

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 (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 (21 to 45 mL) of OMNIPAQUE 300 (300 mg/mL)

80 mL to 120 mL of OMNIPAQUE 350 (350 mg/mL)

Head imaging

by infusion:

120 mL to 250 mL (36 to 75 mL) of OMNIPAQUE 240 (240 mg/mL)

Body imaging

by injection:

50 mL to 200 mL (15 to 60 mL) of OMNIPAQUE 300 (300 mg/mL)

60 mL to 100 mL (18 to 30 mL) of OMNIPAQUE 350 (350 mg/mL)

Body imaging

by infusion:

Up to 250 mL of OMNIPAQUE 240 (240 mg/mL) should be used.

DIGITAL SUBTRACTION 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 into a...
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 ventricles, aorta and most of its larger branches, including the carotids, cerebrals, vertebrals, renal, celiac, mesenteric, and the major peripheral vessels of the limb. Radiographic visualization of these structures is possible only if significant hemodilution occurs.

OMNIPAQUE 350 can be injected intravenously as a rapid bolus to provide arterial visualization using digital subtraction angiography. Preparation of the contrast medium is not considered necessary. OMNIPAQUE 350 has provided diagnostic arteriographic images in about 95% of patients. In some cases, poor arterial visualization may be 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 any 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 intravenous catheter placed preferably in the common or the internal jugular vein, into the superior vena cava. Sometimes the femoral vein is used. (See PRECAUTIONS—General.)

**Adverse Reactions**

**Cardiovascular System**

Cardiovascular system reactions in digital arteriography included transient PVCs (6%) and PACs (6.5%). (See ADVERSE REACTIONS: Intravascular—General.)

**Dosage and Administration**

The usual injection volume of OMNIPAQUE 350 for the intravenous digital 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.

Frequently three or more injections may be required, up to a total volume not to exceed 250 mL at 87.5 gll.

**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.)

**Doseage and Administration**

**Peripheric 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 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. 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 very unusual.

**Precautions**

Pulsation should be present in the artery to be injected. In thrombangiitis obliterans, or ascending infection associated with severe atherosclerosis, angiography should be performed with extreme caution, or 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 any other contrast media.

The most frequent reactions, pain and swelling, were almost exclusively reported after arthrography and hysterosalpingography. (See PRECAUTIONS—General.)

**Adverse Reactions**

**Cardiovascular System**

Cardiovascular system reactions in digital arteriography included transient PVCs (6%) and PACs (6.5%). (See ADVERSE REACTIONS: Intravascular—General.)

**Precautions**

**Dosage and Administration**

**Intravenous**

OMNIPAQUE 140 at a concentration of 140 mg/mL is indicated for use in intravenous 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 intra-arterial 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**

**Cardiovascular System**

Cardiovascular system reactions in digital arteriography included transient PVCs (6%) and PACs (6.5%). (See ADVERSE REACTIONS: Intravascular—General.)

**Radiocontrast Media**

OMNIPAQUE 300 and OMNIPAQUE 350 have osmolalities from approximately 1.8 to 2.2 osmol/kg water and are hypertonic under conditions of use. Adults: OMNIPAQUE 350 is indicated in adults for arteriography and oral pass-thru examination of the gastrointestinal tract. OMNIPAQUE 300 is indicated in adults for arteriography and hysterosalpingography.

**Other Branches of the Aorta**

Vertebral 4-10 2-8

Other Branches of the Aorta 8-25 3-10

Includes subclavian, axillary, iliac, and iliac

**CONTRAINDICATIONS**

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

**WARRNINGS—General**

See SECTION II, WARNINGS—General.

**Precautions—General**

Orally administered iohexol is poorly absorbed from the small intestine, whereas about 85% of the orally administered dose is absorbed from the large intestine. In adults, 75% of the absorbed dose is excreted in the feces within 48 hours and 10% is excreted through the bile. There is a minor elimination by renal excretion. The elimination of the metabolites is mainly via the feces. The metabolites are not nephrotoxic.

**Adverse Reactions**

**Hypersensitivity**

Incidence ≤ 1%: Hematoma at injection site

**Nausea and Vomiting**

Incidence ≤ 1%: Flatulence, diarrhea, nausea, vomiting, abdominal pressure

**Cardiovascular System**

Incidence ≤ 1%: Lightheadedness, syncope

**Respiratory System**

None

**Gastrointestinal System**

Incidence > 1%: None

**Urinary System**

Incidence > 1%: None

**Other**

Incidence > 1%: None

**TOXICITY AND PHARMACOLOGIC ACTIONS**

**Pharmacokinetics**

For pharmacokinetics of excretion in adult, see CLINICAL PHARMACOLOGY—Intravascular.

**Precautions**

Preparatory dehydration is not recommended in the elderly, infants, young children, diabetics or anesthetized patients, or in patients with suspected myeloma.
OVERDOSAGE

The recommended dose of OMNIPAQUE 350 at a concentration of 350 mgI/mL for adult oral pass-

DOSEAGE AND ADMINISTRATION—General

Oral Use

When given rectally, larger volumes may be used.

For contrast enhanced computed tomography of the abdomen in children is 180 mL to 750 mL.

When given rectally, larger volumes may be used.

The dosage of undiluted OMNIPAQUE 350 at a concentration of 350 mgI/mL for adult oral pass-

Adverse Reactions

OMNIPAQUE diluted to concentrations from 9 mgI/mL to 21 mgI/mL, administered orally in conjunc-

In controlled clinical studies involving 54 adult patients for oral pass-thru examination of the gastrointesti-

OMNIPAQUE 350 at a concentration of 350 mgI/mL administered orally or rectally is indicated in children

OMNIPAQUE 350 at a concentration of 350 mgI/mL for adult oral pass-thru examination of the gastrointesti-

Oral administration of OMNIPAQUE is most often associated with mild, transient diarrhea especially

The recommended oral dose of OMNIPAQUE diluted to concentrations of 6 mgI/mL to 9 mgI/mL, for contrast enhanced computed tomography in the abdomen in adults is 50 ml to 100 ml, depending on the nature of the examination and the size of the patient.

The recommended oral dose of OMNIPAQUE diluted to concentrations of 6 mgI/mL to 9 mgI/mL, for contrast enhanced computed tomography of the abdomen in adults is 50 ml to 100 ml, depending on the nature of the examination and the size of the patient.

OMNIPAQUE diluted to concentrations from 6 mgI/mL to 9 mgI/mL administered orally in conjunc-

In controlled clinical studies involving 54 adult patients for oral pass-thru examination of the gastrointesti-

OMNIPAQUE may be diluted with water or beverage as follows:

OMNIPAQUE may be diluted 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

OMNIPAQUE 240 at a concentration of 240 mgI/mL administered orally or rectally is indicated in children

OMNIPAQUE diluted to concentrations from 9 mgI/mL to 21 mgI/mL, administered orally in conjunc-

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OMNIPAQUE may be diluted with water or beverage as follows:
**Hypertension (1%)**.

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

**Pain (7%), headache (3%), and unwell feeling (3%).**

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

Injection of OMNIPAQUE in hysterosalpingography is associated with immediate but transient pain. The recommended dosage of OMNIPAQUE 240 is 50 mL but may vary depending on individual anatomy and/or disease state.

HYSTEROsalpingography.

OMNIPAQUE 240 at a concentration of 240 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. 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: 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.

**Gastrointestinal System:**

Injection of OMNIPAQUE in hysterosalpingography is associated with immediate but 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.

**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. 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 (4%), somnolence and fever each with an individual incidence of 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 will 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 hysterosalpingography.

**Precautions**

See PRECAUTIONS—General.

**Adverse Reactions**

Nervous system: Dizziness (3%) and cold sweats (3%).

**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 140

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

OMNIPAQUE 180

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

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

OMNIPAQUE 240

50 ml glass vial, 240 mg/mL, boxes of 10 (NDC 0407-1412-10)

100 ml glass bottle, 240 mg/mL, boxes of 10 (NDC 0407-1412-20)

OMNIPAQUE 300

100 ml glass bottle, 300 mg/mL, boxes of 10 (NDC 0407-1413-10)

150 ml glass bottle, 300 mg/mL, boxes of 10 (NDC 0407-1413-30)

50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1413-50)

OMNIPAQUE 350

100 ml glass bottle, 350 mg/mL, boxes of 10 (NDC 0407-1414-10)

150 ml glass bottle, 350 mg/mL, boxes of 10 (NDC 0407-1414-30)

200 ml in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1414-90)

OMNIPAQUE 400

100 ml glass bottle, 400 mg/mL, boxes of 10 (NDC 0407-1415-10)

150 ml glass bottle, 400 mg/mL, boxes of 10 (NDC 0407-1415-30)

50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1415-50)

OMNIPAQUE 500

75 ml in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1416-10)

50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1416-20)

OMNIPAQUE 600

100 ml glass bottle, 600 mg/mL, boxes of 10 (NDC 0407-1417-10)

150 ml glass bottle, 600 mg/mL, boxes of 10 (NDC 0407-1417-30)

50 mL in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1417-50)

OMNIPAQUE 750

100 ml glass bottle, 750 mg/mL, boxes of 10 (NDC 0407-1418-10)

150 ml glass bottle, 750 mg/mL, boxes of 10 (NDC 0407-1418-30)

200 ml in +PLUSPAK™ (polymer bottle), boxes of 10 (NDC 0407-1418-90)

**Special Handling and Storage for Polymer Bottles Only:**

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