OMNIPAQUE (iohexol) injection, HCP Important Safety Information

WARNING: RISKS ASSOCIATED WITH INTRATHECAL ADMINISTRATION OF OMNIPAQUE INJECTION 140 mg IODINE/mL and 350 mg IODINE/mL

Use only the OMNIPAQUE iodine concentrations and presentations recommended for intrathecal procedure. Intrathecal administration of OMNIPAQUE of a wrong iodine concentration, even if inadvertent, may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.

INDICATIONS:

OMNIPAQUE is indicated for intrathecal procedures for:

- Myelography and computerized tomography myelography (lumbar, thoracic, cervical, total columnar) in adults and pediatric patients aged 2 weeks and older
- CT cisternography in adults and pediatric patients aged 2 weeks and older

OMNIPAQUE is indicated for intra-arterial procedures for:

- Cardiac ventriculography in adults and pediatric patients
- Aortography including studies of aorta and its branches in adults and pediatric patients
- Selective coronary arteriography in adults
- Cerebral arteriography in adults
- Peripheral arteriography in adults
- Intra-arterial digital subtraction angiography (IA-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults
- Pulmonary angiography in pediatric patients

OMNIPAQUE is indicated for intravenous procedures for:

- Excretory urography in adults and pediatric patients
- CT of the head and body in adults and pediatric patients
- Peripheral venography (phlebography) in adults

- Intravenous digital subtraction angiography (IV-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults

OMNIPAQUE is indicated for oral or rectal procedures for:

- Radiographic examination of the gastrointestinal tract by oral administration in adult patients and by oral or rectal administration in pediatric patients
- CT of the abdomen and pelvis by oral administration in adults and pediatric patients in conjunction with intravenous administration of OMNIPAQUE

OMNIPAQUE is indicated for intraarticular procedures for:

- Arthrography in adults

OMNIPAQUE is indicated for body cavity procedures for:

- Endoscopic retrograde pancreatography and cholangiopancreatography in adults
- Herniography in adults
- Hysterosalpingography in adults
- Voiding cystourethrography in pediatric patients

Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure. See dosing and administration in the prescribing information.

CONTRAINDICATIONS:

OMNIPAQUE for hysterosalpingography is contraindicated during pregnancy or suspected pregnancy, menstruation or when menstruation is imminent, within 6 months after termination of pregnancy, within 30 days after conization or curettage, when signs of infection are present in any portion of the genital tract including the external genitalia, and when reproductive tract neoplasia is known or suspected because of the risk of peritoneal spread of neoplasm.

WARNINGS AND PRECAUTIONS:

Risks Associated with Intrathecal Administration of OMNIPAQUE injection 140 mg iodine/mL and 350mg iodine/mL: Use only the iodine concentrations and presentations recommended for intrathecal procedures. **See Boxed Warning**

Risks Associated with Parenteral Administration of OMNIPAQUE Oral Solution: For oral use only. Adverse reactions such as hemolysis may occur if OMNIPAQUE is administered intravenously or intraarterially due to low osmolality.

Hypersensitivity Reactions: OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk in patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity.

Acute Kidney Injury: Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration.

Cardiovascular Adverse Reactions: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patients with congestive heart failure and have resuscitation equipment and trained personnel available.

Thromboembolic Events: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiography procedures with iodinated contrast agents. Risk factors for thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications. Use meticulous angiographic techniques and minimize length of procedures to minimize events. Avoid blood remaining in contact with syringes containing OMNIPAQUE and avoid angiocardiography in patients with homocystinuria.

Extravasation and Injection Site Reactions: Extravasation of OMNIPAQUE during intravenous or intra-arterial injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure correct placement and monitor patients for extravasation.

Thyroid Storm in Patients with Hyperthyroidism: Thyroid storm has occurred after the intravenous or intra-arterial use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule. Evaluate the risk in these patients before use of OMNIPAQUE.

Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media.

Hypertensive Crisis in Patients with Pheochromocytoma: Hypertensive crisis has occurred after the use of iodinated contrast agents in patients with pheochromocytoma. Monitor patients when administering OMNIPAQUE intravenously or intra-arterially. Use the minimum amount of contrast necessary and monitor blood pressure throughout the procedure.

Sickle Cell Crisis in Patients with Sickle Cell Disease: Iodinated contrast agents when administered intravenously or intra-arterially may promote sickling in individuals who have sickle cell disease. Hydrate patient prior to and following OMNIPAQUE administration and use OMNIPAQUE only if the necessary imaging cannot be obtained with alternative imaging modalities.

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions may develop from 1 hour to several weeks after intravenous or intra-arterial contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis, acute generalized exanthematous pustulosis and drug reaction with eosinophilia and systemic symptoms. Reaction severity may increase and time to onset my decrease with repeat administration of contrast agents. Prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering to patients with a history of severe cutaneous reactions.

Interference with Laboratory Test: OMNIPAQUE can interfere with protein-bound iodine test.

Increased Risk of Seizures with Intrathecal Procedures: Focal and generalized motor seizures have been reported after intrathecal use of iodinated contrast agents. Use of medications that may lower the seizure threshold should be carefully evaluated. Consider discontinuing these agents at least 48 hours before and at least 24 hours following intrathecal administration of OMNIPAQUE.

Most Common Adverse Reactions

Intrathecal Administration: In clinical trials ≥1% of 1,531 adult patients included: headaches, pain (including backache, neckache, stiffness, and neuralgia), nausea, vomiting and dizziness. In clinical trials ≥1% of 152 pediatric patients included headache, vomiting and backache.

Intra-arterial or Intravenous Administration: In clinical trials ≥1% of 1,485 adult patients included arrhythmias (including PVCs and PACs), pain, vision abnormalities (including blurred vision and photomas), taste perversion and nausea. In clinical trials ≥1% of 391 pediatric patients included vomiting and nausea.

Oral or Rectal Administration for Examination of the Gastrointestinal Tract: In clinical trials ≥1% of 54 adult patients included diarrhea, nausea, vomiting, abdominal pain, flatulence and headache. In clinical trials ≥1% of 58 pediatric patients included diarrhea, vomiting, nausea, abdominal pain, fever, urticaria and hypotension.

Oral Administration for CT of the Abdomen in Conjunction with Intravenous Administration: In clinical trials ≥1% of 44 adults patients included a single report of vomiting. In clinical trials ≥1% of 69 pediatric patients included a single report of vomiting.

Intraarticular Administration: In clinical trials ≥1% of 285 adult patients included administration site pain, swelling and heat.

Body Cavity Use: No new adverse reactions were associated with the use of OMNIPAQUE in 51 pediatric patients.

Drug-Drug Interactions:

In patients with renal impairment, metformin can cause lactic acidosis.

OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE.

Pregnancy and Lactation:

There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth.

Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.

Please see the full Prescribing Information, including boxed warning and additional Important Safety Information at (add link)

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

Indication and Important Safety Information by Indication

Indication	Safety
OMNIPAQUE is indicated for intrathecal procedures for: • Myelography and computerized tomography myelography (lumbar, thoracic, cervical, total columnar) in adults and pediatric patients aged 2 weeks and older • CT cisternography in adults and pediatric patients aged 2 weeks and older Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure. See dosing and administration in the prescribing information.	**WARNING: RISKS ASSOCIATED WITH INTRATHECAL ADMINISTRATION OF OMNIPAQUE INJECTION 140 mg IODINE/mL and 350 mg IODINE/mL** **Use only the OMNIPAQUE iodine concentrations and presentations recommended for intrathecal procedure. Intrathecal administration of OMNIPAQUE of a wrong iodine concentration, even if inadvertent, may cause death, convulsions, seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.** **WARNINGS AND PRECAUTIONS**: **Risks Associated with Intrathecal Administration of OMNIPAQUE injection 140 mg iodine/mL and 350 mg iodine/ml:** Use only the iodine concentrations and presentations recommended for intrathecal procedures. **See Boxed Warning** **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk is patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration.

	Cardiovascular Adverse Reactions: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available. **Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age**: Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media. **Interference with Laboratory Test**: OMNIPAQUE can interfere with protein-bound iodine test. **Increased Risk of Seizures with Intrathecal Procedures**: Focal and generalized motor seizures have been reported after intrathecal use of iodinated contrast agents. Use of medications that may lower the seizure threshold should be carefully evaluated. Consider discontinuing these agents at least 48 hours before and at least 24 hours following intrathecal administration of OMNIPAQUE. **Most Common Adverse Reactions** Intrathecal Administration: In clinical trials ≥1% of 1,531 adult patients included: headaches, pain (including backache, neckache, stiffness, and neuralgia), nausea, vomiting and dizziness. In clinical trials ≥1% of 152 pediatric patients included headache, vomiting and backache. **Drug-Drug Interactions**: In patients with renal impairment, metformin can cause lactic acidosis. OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**:

	There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.
OMNIPAQUE is indicated for intra-arterial procedures for: • Cardiac ventriculography in adults and pediatric patients • Aortography including studies of aorta and its branches in adults and pediatric patients • Selective coronary arteriography in adults • Cerebral arteriography in adults • Peripheral arteriography in adults • Intra-arterial digital subtraction angiography (IA-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults • Pulmonary angiography in pediatric patients Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended	**WARNINGS AND PRECAUTIONS**: **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk is patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration. **Cardiovascular Adverse Reactions**: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available.

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	Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions may develop from 1 hour to several weeks after intravenous or intra-arterial contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis, acute generalized exanthematous pustulosis and drug reaction with eosinophilia and systemic symptoms. Reaction severity may increase and time to onset my decrease with repeat administration of contrast agents. Prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering to patients with a history of severe cutaneous reactions. **Interference with Laboratory Test**: OMNIPAQUE can interfere with protein-bound iodine test. **Most Common Adverse Reactions** Intra-arterial or Intravenous Administration: In clinical trials ≥1% of 1,485 adult patients included arrhythmias (including PVCs and PACs), pain, vision abnormalities (including blurred vision and photomas), taste perversion and nausea. In clinical trials ≥1% of 391 pediatric patients included vomiting and nausea. **Drug-Drug Interactions**: In patients with renal impairment, metformin can cause lactic acidosis. OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**: There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.

OMNIPAQUE is indicated for intravenous procedures for: • Excretory urography in adults and pediatric patients • CT of the head and body in adults and pediatric patients • Peripheral venography (phlebography) in adults • Intravenous digital subtraction angiography (IV-DSA) of the head, neck, abdominal, renal, and peripheral vessels in adults Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure. See dosing and administration in the prescribing information.	**WARNINGS AND PRECAUTIONS**: **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk is patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration. **Cardiovascular Adverse Reactions**: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available. **Extravasation and Injection Site Reactions**: Extravasation of OMNIPAQUE during intravenous or intra-arterial injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure correct placement and monitor patients for extravasation. **Thyroid Storm in Patients with Hyperthyroidism**: Thyroid storm has occurred after the intravenous or intra-arterial use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule. Evaluate the risk in these patients before use of OMNIPAQUE.

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	OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**: There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.
OMNIPAQUE is indicated for oral or rectal procedures for: • Radiographic examination of the gastrointestinal tract by oral administration in adult patients and by oral or rectal administration in pediatric patients • CT of the abdomen and pelvis by oral administration in adults and pediatric patients in conjunction with intravenous administration of OMNIPAQUE Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure.	**WARNINGS AND PRECAUTIONS**: **Risks Associated with Parenteral Administration of OMNIPAQUE Oral Solution:** For oral use only. Adverse reactions such as hemolysis may occur if OMNIPAQUE is administered intravenously or intraarterially due to low osmolality. **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk in patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age**: Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media. **Interference with Laboratory Test**: OMNIPAQUE can interfere with protein-bound iodine test. **Most Common Adverse Reactions**

See dosing and administration in the prescribing information.	Oral or Rectal Administration for Examination of the Gastrointestinal Tract: In clinical trials ≥1% of 54 adult patients included diarrhea, nausea, vomiting, abdominal pain, flatulence and headache. In clinical trials of 58 pediatric patients included diarrhea, vomiting, nausea, abdominal pain, fever, urticaria and hypotension. Oral Administration for CT of the abdomen with Intravenous Administration: In clinical trials of 44 adults and 69 pediatric patients included vomiting. **Drug-Drug Interactions**: In patients with renal impairment, metformin can cause lactic acidosis. OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**: There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.
OMNIPAQUE is indicated for intraarticular procedures for: • Arthrography in adults	**WARNINGS AND PRECAUTIONS**: **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk is patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment,

	dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration. **Cardiovascular Adverse Reactions**: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available. **Interference with Laboratory Test**: OMNIPAQUE can interfere with protein-bound iodine test. **Most Common Adverse Reactions** Intraarticular Administration: In clinical trials ≥1% of 285 adult patients included administration site pain, swelling and heat. **Drug-Drug Interactions**: In patients with renal impairment, metformin can cause lactic acidosis. OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**: There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal

	intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.
OMNIPAQUE is indicated for body cavity procedures for: • Endoscopic retrograde pancreatography and cholangiopancreatography in adults • Herniography in adults • Hysterosalpingography in adults • Voiding cystourethrography in pediatric patients Specific dosage forms, concentrations and presentations of OMNIPAQUE are recommended for each type of imaging procedure. See dosing and administration in the prescribing information.	**CONTRAINDICATIONS**: OMNIPAQUE for hysterosalpingography is contraindicated during pregnancy or suspected pregnancy, menstruation or when menstruation is imminent, within 6 months after termination of pregnancy, within 30 days after conization or curettage, when signs of infection are present in any portion of the genital tract including the external genitalia, and when reproductive tract neoplasia is known or suspected because of the risk of peritoneal spread of neoplasm. **WARNINGS AND PRECAUTIONS**: **Hypersensitivity Reactions:** OMNIPAQUE can cause life-threating or fatal hypersensitivity reactions including anaphylaxis. Most severe reactions develop shortly after the start of the injection (within 1 to 3 minutes), but delayed reactions can also occur. There is an increased risk is patients with a history of a previous reaction to contrast agent and known allergic disorders or other hypersensitivities. Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both incidence and severity. **Acute Kidney Injury:** Acute kidney injury, including renal failure, may occur after parenteral administration of OMNIPAQUE. Risk factors include pre-existing renal impairment, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinaceous diseases, repetitive and/or large doses of an iodinated contrast agent. Use lowest dose in patients with renal impairment. Adequately hydrate patients prior to administration and do not use laxatives, diuretics, or preparatory dehydration prior to OMNIPAQUE administration. **Cardiovascular Adverse Reactions**: Life-threatening or fatal cardiovascular reactions including hypotension, shock, cardiac arrest have occurred with the parenteral administration of OMNIPAQUE. Most deaths occur during the injection or 5-10 minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest dose necessary in patient with congestive heart failure and have resuscitation equipment and trained personnel available.

	Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age: Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media. **Interference with Laboratory Test**: OMNIPAQUE can interfere with protein-bound iodine test. **Most Common Adverse Reactions** Body Cavity Use: No new adverse reactions were associated with the use of OMNIPAQUE in 51 pediatric patients. **Drug-Drug Interactions**: In patients with renal impairment, metformin can cause lactic acidosis. OMNIPAQUE may interfere with thyroid uptake of radioactive iodine and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post OMNIPAQUE. **Pregnancy and Lactation**: There are no data with iohexol use in pregnant women. Published literature report intravenously iohexol crosses the placenta and is visualized in the digestive tract of exposed infants after birth. Published literature reports that breast feeding after intravenous iohexol administration to the mother would result in the infant receiving an oral dose of approximately 0.7% of the maternal intravenous dose. Lactating women may consider pumping and discarding breast milk for 10 hours after OMNIPAQUE administration to minimize drug exposure to the breastfed infant.