ISOVUE®-300, -370 (Iopamidol) Injection Imaging Bulk Package

INDICATION

ISOVUE®-300, -370 (Iopamidol) Injection Imaging Bulk Package is indicated for:

- Angiography in adults throughout the cardiovascular system including cerebral and peripheral arteriography, coronary arteriography and ventriculography, selective visceral arteriography and aortography
- Angiocardiography in pediatric patients
- Intravenous excretory urography in adult and pediatric patients
- Contrast enhancement of computed tomographic (CECT) head and body imaging in adults and pediatric patients
- Peripheral venography in adults

For use only with an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with ISOVUE-300, -370 Imaging Bulk Package.

ISOVUE-300, -370 Imaging Bulk Package is NOT FOR INTRATHECAL USE.
WARNING: RISKS ASSOCIATED WITH INTRATHECAL ADMINISTRATION
Intrathecal administration, even if inadvertent, can cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. ISOVUE is for intra-arterial or intravenous use only.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risks Associated with Intrathecal Administration

Intrathecal administration, even if inadvertent, can cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. ISOVUE is for intra-arterial or intravenous use only and must not be administered intrathecally.

Hypersensitivity Reactions

ISOVUE can cause life-threatening or fatal hypersensitivity reactions including anaphylaxis. Manifestations include respiratory arrest, laryngospasm, bronchospasm, angioedema, and shock. Most severe reactions develop shortly after the start of injection (e.g., within 1 to 3 minutes), but delayed reactions can also occur. There is increased risk of hypersensitivity reactions in patients with a history of previous reactions to contrast agents, and allergic disorders (i.e., bronchial asthma, allergic rhinitis, and food allergies) or other hypersensitivities. Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents and always have emergency resuscitation

equipment and trained personnel available prior to ISOVUE administration. Monitor all patients for hypersensitivity reactions.

Acute Kidney Injury
Acute kidney injury, including renal failure, may occur after ISOVUE administration. Risk factors include: pre-existing renal insufficiency, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma or other paraproteinemias, and repetitive or large doses of ISOVUE. Use the lowest necessary dose of ISOVUE in patients with renal impairment. Adequately hydrate patients prior to and following ISOVUE administration. Do not use laxatives, diuretics, or preparatory dehydration prior to ISOVUE administration.

Cardiovascular Adverse Reactions
ISOVUE increases the circulatory osmotic load and may induce acute or delayed hemodynamic disturbances in patients with congestive heart failure, severely impaired renal function, combined renal and hepatic disease, and combined renal and cardiac disease, particularly when repetitive or large doses are administered. Fatal cardiovascular reactions have occurred mostly within 10 minutes of ISOVUE injection; the main feature was cardiac arrest with cardiovascular disease as the main underlying factor. Hypotensive collapse and shock have occurred. Cardiac decompensation, serious arrhythmias, and myocardial ischemia or infarction can occur during coronary arteriography and ventriculography. Use the lowest necessary dose of ISOVUE in patients with congestive heart failure and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

Thromboembolic Events
Serious, in some cases fatal, thromboembolic events, including myocardial infarction and stroke, can occur during angiographic procedures. During these procedures, increased thrombosis and activation of the complement system occurs. Risk factors for developing thromboembolic events include: length of procedure, catheter and syringe material, underlying disease state, and concomitant medications. To minimize thromboembolic events, use meticulous angiographic techniques and minimize the length of the procedure. Avoid blood remaining in contact with syringes containing iodinated contrast agents, which increases risk of clotting. Avoid angiocardiography in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Extravasation and Injection Site Reactions
Extravasation can occur with ISOVUE administration, particularly in patients with severe arterial or venous disease. Inflammation, blistering, skin necrosis,

and compartment syndrome have been reported following extravasation. In addition, injection site reactions such as pain and swelling at the injection site can also occur. Ensure intravascular placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

Thyroid Storm in Patients with Hyperthyroidism
Thyroid storm has occurred after the intravascular use of iodinated agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of ISOVUE.

Thyroid Dysfunction in Pediatric Patients 0 Years 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 agents in pediatric patients 0 years to 3 years of age. Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after iodinated contrast agent exposure. Pediatric patients with congenital cardiac conditions may be at greatest risk given that they often require high doses of contrast during invasive cardiac procedures. An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to iodinated contrast agents, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

Hypertensive Crisis in Patients with Pheochromocytoma
Hypertensive crisis in patients with pheochromocytoma has occurred with iodinated contrast agents. Closely monitor patients when administering ISOVUE if pheochromocytoma or catecholamine-secreting7 of 13 paragangliomas are suspected. Inject the minimum amount of ISOVUE necessary and have measures for treatment of hypertensive crisis readily available.

Sickle Cell Crisis in Patients with Sickle Cell Disease
Iodinated contrast agents can promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following ISOVUE administration and use only if the necessary imaging information cannot be obtained with alternative imaging modalities.

Severe Cutaneous Adverse Reactions
Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN),

acute generalized exanthematous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of a contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering ISOVUE to patients with a history of a severe cutaneous adverse reaction to ISOVUE.

Interference with Laboratory Tests
ISOVUE can interfere with protein-bound iodine test.

ADVERSE REACTIONS
The most frequent adverse reactions are pain, hot flashes, burning sensation, nausea, and warmth.

DRUG INTERACTIONS
Metformin: In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis, possibly as a result of worsening renal function.

Radioactive Iodine: Administration of ISOVUE may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy. Avoid thyroid therapy or testing for up to 6 weeks post ISOVUE.

USE IN SPECIFIC POPULATIONS
Geriatric Use: Iopamidol is excreted by the kidney, and the risk of adverse reactions to ISOVUE may be greater in patients with renal impairment. Because patients 65 years of age and older are more likely to have renal impairment, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment: The clearance of iopamidol decreases with increasing degree of renal impairment and results in delayed opacification of the urinary system. In addition, preexisting renal impairment increases the risk for acute kidney injury. Iopamidol can be removed by dialysis.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for ISOVUE® Imaging Bulk Package products.

ISOVUE Imaging Bulk Package is currently manufactured for Bracco Diagnostics Inc. at three locations: BIPSO GmbH, Singen (Germany), Patheon Italia S.p.A., Ferentino (Italy), and S. M. Farmaceutici SRL, Tito (Italy).

ISOVUE is a registered trademark of Bracco Diagnostics Inc.

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