ISOVUE-M® 200, 300 (Iopamidol) Injection

INDICATION

ISOVUE-M® 200, 300 (Iopamidol) Injection is a radiographic contrast agent for intrathecal administration only. It is indicated for:

- Lumbar and thoracic myelography and computed tomography (CT) myelography in adults and pediatric patients aged 2 years and older
- Cervical and total columnar myelography in adults
- CT cisternography in adults

CONTRAINDICATION

Intrathecal administration of corticosteroids with iopamidol is contraindicated. Because of overdosage considerations, immediate repeat myelography in the event of technical failure is contraindicated. Myelography should not be performed in the presence of significant local or systemic infection where bacteremia is likely.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

The need for myelographic examination should be carefully evaluated. Caution should be taken when administering ISOVUE-M to patients with increased intracranial pressure or suspicion of intracranial tumor, abscess or hematoma, those with a history of convulsive disorder, severe cardiovascular disease, chronic alcoholism, or multiple sclerosis, and elderly patients.

Particular attention must be given to the state of hydration, concentration of medium, dose, and technique used in these patients.

Risk of Neurotoxicity

Prevent inadvertent intracranial entry of a large or concentrated bolus of the contrast medium which can increase the risk of neurotoxicity through careful patient management. Avoid rapid dispersion of the medium causing inadvertent rise to intracranial levels (e.g., by active patient movement). If intracranial entry of the medium occurs, prophylactic anticonvulsant treatment with diazepam or barbiturates orally for 24 to 48 hours should be considered.

Lowered Seizure Threshold

Phenothiazine derivatives, including those used for their antihistaminic properties; tricyclic antidepressants; MAO inhibitors; CNS stimulants; analeptics; and antipsychotic agents should be carefully evaluated as they may lower the seizure threshold. Consider discontinuing the use of these medications at least 48 hours before and for at least 24 hours following intrathecal use.

Focal and Generalized Motor Seizures
In several cases where higher than recommended doses of iopamidol were administered, focal and generalized motor seizures were reported. Therefore avoid:

- Deviations from recommended neuroradiologic procedure or patient management.
- Use in patients with a history of epilepsy unless medically justified.
- Overdosage.
- Intracranial entry of a bolus or premature diffusion of a high concentration of the medium.
- Failure to maintain elevation of the head during the procedure, on the stretcher, and in bed.
- Excessive and particularly active patient movement or straining.

Hypersensitivity /Anaphylaxis
Patients at increased risk include those with a history of a previous reaction to a contrast medium, with a known sensitivity to iodine, with known clinical hypersensitivities (i.e. bronchial asthma, hay fever, and food allergies). A thorough medical history with emphasis on allergy and hypersensitivity, prior to the injection of any contrast medium, may be more accurate than pretesting in predicting potential adverse reactions.

Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions, but may reduce their incidence and severity.

Acute Kidney Injury
Acute kidney injury, including renal failure, may occur after administration of iodinated contrast agents. Use the lowest dose of ISOVUE-M, especially in patients with risk factors for acute kidney injury. Adequately hydrate patients prior to and following ISOVUE-M administration.

Cardiovascular Adverse Reactions
Iodinated contrast agents increase 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. Use the lowest necessary dose in patients with congestive heart failure and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

Thyroid Storm in Patients with Hyperthyroidism
Thyroid storm has occurred after the use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule.

Thyroid Dysfunction 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. After exposure to iodinated contrast agent, individualize thyroid function monitoring based on underlying risk factors. ISOVUE-M is not indicated for use in pediatric patients younger than 2 years of age.

Sickle Cell Crisis in Patients with Sickle Cell Disease
Iodinated contrast agents may promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following ISOVUE-M 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 administration of iodinated contrast agent. Avoid administering ISOVUE-M to patients with a history of a severe cutaneous adverse reaction to ISOVUE-M.

DRUG INTERACTION
Many radiopaque contrast agents are incompatible in vitro with some antihistamines and many other drugs. No other pharmaceuticals should be admixed with iopamidol. Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis. Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine; therefore avoid thyroid therapy or testing for up to 6 weeks post administration. ISOVUE-M can interfere with protein-bound iodine test.

ADVERSE REACTIONS
The most frequent adverse reactions are headache, nausea, vomiting, and musculoskeletal pain.

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-M® products.

ISOVUE-M 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-M is a registered trademark of Bracco Diagnostics Inc.

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