ISOVUE-M® 200, 300 (Iopamidol Injection)

INDICATION:

ISOVUE-M® 200, 300 (Iopamidol Injection) is indicated for intrathecal administration in adult neuroradiology including myelography (lumbar, thoracic, cervical, total columnar), and for contrast enhancement of computed tomographic (CECT) cisternography and ventriculography. ISOVUE-M® 200 is indicated for thoraco-lumbar myelography in children over the age of two years.

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. Some physicians have discontinued these agents 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 a known clinical hypersensitivity (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 to avoid or minimize possible allergic reactions in such patients should be considered.

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.

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).

Bracco Diagnostics Inc.

510 Carnegie Center
Suite 300
Princeton, NJ 08540 USA
Phone: 609-514-2200
Toll-Free: 1-877-272-2269 (U.S. only)
Fax: 609-514-2446