WARNINGS
Severe Adverse Events—lnadvertent Intrathecal Administration
Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated radiopaque diagnostic agents. Such adverse reactions may be severe enough to cause death.

Special attention must be given to ensure that the drug product is not inadvertently administered intrathecally.

Caution must be exercised in patients with severely impaired renal function, those with combined renal and hepatic failure, and in patients on chronic hemodialysis or peritoneal dialysis. Patients who have a history of myeloproliferative disorders may be at higher risk of hemolytic anemia. Special precautions are required.

Contrast media may promote sickling in individuals who are homozygous for sickle cell disease.

Reports of thyroid storm following the use of iodinated radiopaque diagnostic agents in patients with hyperthyroidism or prior induction of thyroid storm with thyroid stimulating hormone suggest that this additional risk be evaluated in such patients before use of any contrast medium.

Enhancement is thus due to the relative differences in extravascular diffusion between normal and abnormal tissue, quite independent of the intravascular contrast agent; it may be malignant, benign, or normal tissue, but would probably not be a cyst, hematoma, or other nonvascular lesion.

CLINICAL PHARMACOLOGY
ISOVUE may be used to refine diagnostic precision in areas of the brain which may not otherwise have been satisfactorily visualized.

Nonneoplastic Conditions
Arteriovenous malformations and aneurysms will show contrast enhancement. For these vascular lesions, the enhancement is probably dependent on the iodine content of the circulating blood pool. Contrast enhancement appears to be greatest within 60 to 90 seconds after bolus administration. In normal subjects, approximately one percent or less of the administered dose appears in cumulative 72- to 96-hour fecal specimens.

Animal studies indicate that iopamidol does not cross the blood-brain barrier to any significant extent. Bracco s.p.a. is not aware of any reports of ophthalmic adverse reactions in humans associated with the use of iopamidol.

INDICATIONS AND USAGE
The use of iopamidol in the image intensifier of an angiographic system is not recommended.

Isovue® (Iopamidol Injection) enhances computed tomographic brain imaging through contrast enhancement. It is used in patients with cerebral infarctions studied from one to four weeks from the onset of symptoms.

Diabetes mellitus is a condition of chronic hyperglycemia (elevated blood glucose) that is often associated with disturbances of carbohydrate, fat, and protein metabolism. The primary means of treatment of diabetes is dietary control along with regular physical activity and exercise. In recent years, different forms of insulin therapy have become widely used. The two main types of diabetes are type 1 (insulin-dependent diabetes mellitus, or IDDM) and type 2 (non-insulin-dependent diabetes mellitus, or NIDDM). Type 2 diabetes, which accounts for 90% to 95% of all cases of diabetes, is characterized by a relative or absolute deficiency of insulin.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are a group of drugs that relieve pain, reduce inflammation, and lower fever. They are often used to treat arthritis, osteoarthritis, and rheumatoid arthritis. In addition to their anti-inflammatory effects, NSAIDs can also have analgesic and antipyretic effects. NSAIDs are available in both prescription and over-the-counter (OTC) forms. Common NSAIDs include aspirin, ibuprofen, naproxen, and diclofenac.

The use of NSAIDs is associated with an increased risk of gastrointestinal side effects, particularly ulcers and bleeding, and the risk may be additive with the use of other risk factors such as corticosteroids and a history of peptic ulcer disease. NSAIDs also increase the risk of bleeding and may alter the antithrombotic properties of aspirin and other antiplatelet drugs. In patients with a history of peptic ulcer disease or other gastrointestinal disorders, the use of a protective agent such as a proton pump inhibitor (PPI) may be considered.

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The results of P&L and injection site area stability studies, which depend on clinical experience, show that this agent is effective in the treatment of isolated or chemotherapy-induced thrombosis, and that it is safe in the administration of subcutaneous or intramuscular contrast media. However, clinical studies in patients suffering from pulmonary embolism were not conducted to determine the safety and efficacy of this agent.

Any test which might be affected by contrast media should be performed prior to use of this product.

Laboratory Test Package

Iopamidol solutions have been shown to cause reactions of the skin, such as pruritus or urticaria, in some patients. However, there is no significant increase in the number of these reactions when compared to reactions to other iodinated contrast media. During intravenous administration, the incidence of these reactions appears to be approximately the same as that observed with other iodinated contrast media. These reactions are generally mild and transient. In the event of any adverse reactions, the patient should be treated with appropriate supportive measures.

PREGNANCY/BREASTFEEDING

The safety of this contrast medium for use in pregnancy has not been established. The safety of this contrast medium for use in breastfeeding has not been established. When the possibility of a fetal exposure cannot be ruled out, the use of this contrast medium should be avoided. When the possibility of a fetal exposure can be ruled out, the use of this contrast medium may be considered.

Pediatric Use

Iopamidol is generally not recommended for use in children. However, in certain circumscribed circumstances, its use may be considered. For example, in patients with acute or chronic renal failure, the use of this contrast medium may be considered when the potential benefits outweigh the potential risks of its use.

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