Selective Visceral Arteriography and Aortography
Pediatric Angiocardiography

Fatalities, mostly of cardiovascular origin, have occurred. Reported incidences of death from the administration of other iodinated contrast media range from 6.6 per 1 million (0.00066 percent) to 1 in 10,000 (0.005 percent) patients. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Chemotoxic reactions result from the physicochemical properties of the contrast medium, the... reactions are included in this category.

Experience with iopamidol suggests there is much less discomfort (e.g. pain and/or warmth) noted with peripheral arteriography. Fewer changes are noted in ventricular function after... delayed allergic reactions are more frequent in patients undergoing... idiosyncratic reactions include all other reactions. They occur more commonly in patients undergoing... allergic reactions involving the skin, may uncommonly occur within 2-3 days (range 1-7 days) after the administration of contrast (see...

Iopamidol Injection is also available as ISOVUE-M... also be used. The total dose for either CECT procedure should not exceed 60 grams of iodine.

Drug Incompatibilities
Many radiopaque contrast agents are incompatible with... incompatibilities with many other drugs; therefore, no other pharmaceuticals should be admixed with contrast agents.

HOW SUPPLIED
ISOVUE (lopamidol Injection) formulations are stable, aqueous, sterile, and nonpyrogenic solutions for intravascular administration. ISOVUE (lopamidol Injection) is designated chemically as (3′,4′-Iopamido)-2′-(2-hydroxyethyl)-1′-(2-hydroxyethyl)ethyl]-3,4-dihydro-2H-1,4-benzoxazepine-2,4-dione. Structural formula:

CLINICAL PHARMACOLOGY
Excretory Urography
System, Including Cerebral and Peripheral Arteriography,

Also Available... ISOVUE 200, 250, 300 and 370 are NOT FOR INTRATHECAL USE.

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Example: The combined total dose for multiple injections has not exceeded 350 mL.

OVERDOSAGE
As with all radiopaque contrast agents, only the lowest dose of ISOVUE necessary to obtain adequate visualization should be used. A lower dose reduces the possibility of an adverse reaction. Most procedures do not require use of either a maximum dose or the highest... 100 mL and for ISOVUE-370 is 40 mL administered by rapid intravenous injection.

Intravascular Injection
For angiographic use, intravenous injection of ISOVUE is rarely indicated. However, it may be used for diagnostic purposes, as indicated below, in the treatment of certain patients with renal failure. The usual adult dose is 100 mL for ISOVUE-250 and 75 mL for ISOVUE-300.

Intrathecal Injection
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PRECAUTIONS

General

Diagnostic procedures which involve the use of any radiopaque agent should be carried out under the direction of a qualified radiologist. The use of appropriate diagnostic techniques and equipment is essential to minimize the risk of complications (see "Adverse Reactions"). Any test which might be affected by contrast media should be performed prior to administration of the contrast medium.

In angiographic procedures, the possibility of dislodging plaques or damaging or perforating arteries or veins should be borne in mind during catheter manipulations and contrast medium injection. Test injections to ensure proper catheter placement are suggested. Selective coronary arteriography should be performed only in selected patients and those otherwise have been satisfactorily visualized.

Drug/Laboratory Test Interactions

The results of PBI and radioactive iodine uptake studies, which depend on iodine estimations, will not accurately reflect the thyroid function of patients who have received contrast media. Any test which might be affected by contrast media should be performed prior to administration of the contrast medium.

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported following administration of iodinated contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. Numerous factors, including length of procedure, catheter and syringe material, underlying disease state, and concomitant medications may contribute to the development of thromboembolic events. For these reasons, the use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of clotting.

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In vitro tests on various blood clotting parameters and clotting factors have been performed using an in vitro method in which plasma was obtained from patients who had received intravenously administered contrast media. The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.

Other drugs should not be admixed with iopamidol. The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of clotting.

Skin and Appendages

Daily Skin Changes: none rash

Severe Cutaneous Adverse Reactions:

Nervous System

Neurologic pain (2.8%) vasovagal reaction

Sensory: burning sensation (1.4%) tingling in arms, neck, legs, face

Gastrointestinal

Nausea (6%) vomiting (1%)

Skin and Appendages

None rash

Urogenital

None urinary retention

Respiratory

None

Immunologic

None

Musculoskeletal

None

Intravascular

Local Reactions: Injection site pain and swelling may occur. In the majority of cases it is transient (1-3 days). The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of clotting.

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