The usual dose range for single injections is provided in the following table:

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Usual Dose Range</th>
<th>Usual Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-9 years</td>
<td>15-30 mL</td>
<td>50 mL</td>
</tr>
<tr>
<td>10-18 years</td>
<td>20-50 mL</td>
<td>100 mL</td>
</tr>
<tr>
<td>5-9 years</td>
<td>100 mL</td>
<td></td>
</tr>
</tbody>
</table>

**Cerebral Arteriography**
- ISOVUE-200 (lopamidol Injection, 200 mgl/mL) should be used. The usual dose is 25 to 150 mL.
- Doses up to a total of 250 mL have been administered during peripheral arteriography.

**Pediatric Angiocardiography, Selective Visceral Arteriography and Aortography**
- ISOVUE-200 (lopamidol Injection, 200 mgl/mL) should be used. The usual dose is 25 to 150 mL.
- Doses up to a total of 250 mL have been administered during peripheral arteriography.

**Pediatric Excretory Urography**
- ISOVUE-250 or ISOVUE-300 may be used. The dosage recommended for use in children for excretory urography is 1.2 mL/kg to 1.6 mL/kg, for ISOVUE-250, and 1.0 mL/kg to 3.0 mL/kg for ISOVUE-300.

**Contrast Medium Properties**
- Specific Gravity: 1.227 (37°C), 1.281 (20°C), 1.339 (37°C), 1.405 (20°C)
- Viscosity: 2.0 (37°C), 3.0 (20°C), 4.7 (37°C), 9.4 (20°C)
- Osmolality: 413 (37°C), 524 (20°C), 616 (37°C), 796 (20°C)
- MW: 777.09
- CAS: 60166-93-0
- Organically Bound Iodine: 49%
- Maximum Injection Rate: 2.5 mL/sec
- Maximum IV Injection Rate: 2.5 mL/sec
- Maximum IV Rate (Pediatric): 2.5 mL/min/kg
- Maximum IV Rate (Adult): 5 mL/min/kg
- Use in Hemodynamic Shock: Maximum rate limited to 0.5 mL/min/kg
- Maximum IV Rate for Selective Angiography: 2.5 mL/min/kg

**Contraindications**
- Hypersensitivity to the drug or to any of its components.
- Known familial or personal history of hypothyroidism.
- Known history of allergy to radiopaque iodine-containing compounds.

**Warnings**
- Cardiac arrhythmias may occur with injection rates above 1.0 mL/sec.
- Overdose is unlikely, but EKG monitoring is recommended.
- Propylene glycol is used as a solvent; it should be considered in patients with a history of allergy to propylene glycol or sorbitol.

**Adverse Reactions**
- The incidence of adverse reactions is very low and is generally associated with injection rates above 1.0 mL/sec.
- Common local reactions include stinging, burning, and pain at the injection site.
- Systemic reactions are rare and may include hypotension, tachycardia, and atrial fibrillation.

**Pregnancy and Lactation**
- Category B: Animal reproduction studies have not been done, nor are they practical. Animal studies do not indicate potential human risk. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

**Pediatric Use**
- Safety and efficacy in children have not been established.

**Overdosage**
- There is no specific antidote for iopamidol. Symptomatic and supportive treatment should be provided.

**Pharmacology**
- Iopamidol is mainly excreted by the kidneys, with a small portion metabolized by the liver.
- The elimination half-life is approximately two hours; the half-life is not dose dependent.

**Mechanism of Action**
- Iopamidol is a non-ionic, water-soluble, contrast agent that enhances x-ray absorption.

**Preparation of Solution**
- ISOVUE-200 (lopamidol Injection, 200 mgl/mL) should be used. The usual dose is 25 to 150 mL.
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**Stability**
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**INDICATIONS AND USAGE**

ISOVUE (lopamidol Injection) is indicated for angiography throughout the cardiovascular system, including cerebral and peripheral vascular sites and other locations where contrast enhancement of computed tomographic (CECT) head and body imaging (see below).

**Urogenital**

None.

**Patients receiving injectable radiopaque diagnostic agents should be instructed to:**

1. Inform your physician if you are pregnant.
2. Inform your physician if you are diabetic or if you have multiple myeloma, pheochromocytoma, or a history of allergy to or intolerance of iodinated contrast media.

**Regardless of the contrast agent employed, the overall estimated incidence of serious adverse reactions following contrast media injection is approximately 0.1% (10 per 10,000 exposures).**

**Dosage**

The dosage of ISOVUE is determined by the contrast enhancement required by the procedure. ISOVUE is available for injection in single-use ampules in a concentration of 300 mg of iopamidol per milliliter. The amount to be administered should be calculated from the following formula:

\[
\text{Volume (ml)} = \frac{\text{Desired dose (mg/kg)}}{300} 
\]

**Use**

ISOVUE should not be used in patients with history of a sensitivity to iodine per se, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies). The occurrence of severe idiosyncratic or anaphylactoid reactions associated with iodinated contrast media has been reported. These reactions are characterized by shortness of breath, pulmonar y edema, hypotension, circulatory collapse, and anaphylactic reactions. Reactions are more likely to occur in patients with a history of sensitivity to iodinated contrast media. Therefore, any patient with a history of sensitivity to iodinated contrast media should be carefully monitored during injection and for at least 30 minutes thereafter for the occurrence of adverse reactions, which may be severe and sometimes fatal, and the nature and extent of which are unpredictable.

**Contraindications**

**Adverse Reactions**

**General**

Adverse reactions have been reported due to the inadvertent intravenous injection of ISOVUE. Reactions have been characterized by nausea, vomiting, allergic symptoms with or without angioedema, hemodynamic instability, hypotension, chest discomfort, anxiety, facial edema, angioedema, and pruritus. In a few cases, reactions have been life-threatening and occasionally fatal. In the majority of cases, the reactions were mild or moderate and resolved without sequelae. A few patients required pressor support or corticosteroids. The probability of clinical reactions is directly related to the dose administered. In general, reactions are more likely to occur when the contrast agent is used in higher doses and when a dilution is not possible. Adverse reactions have been reported following extravasation of the contrast agent. Erythema, swelling, and pain at the injection site, redness, urticaria, and gangrene have been reported. The skin may turn bluish or purplish in color. Other reactions include rashes, itching, hypotension, and tachycardia. The mechanism of these reactions is unknown.

**Drug/Laboratory Test Interactions**

**Laboratory Test Findings**

None.

Iopamidol is not known to interfere with the results of any laboratory test. However, changes in laboratory test results may occur with the concurrent administration of drugs that affect renal function. The use of contrast media may result in changes in the results of laboratory tests that are performed after the administration of contrast media. These changes may be related to the concentration and volume of contrast media administered, to the length of time the contrast media are in contact with the body fluid, and to the effect of the contrast media on the regulatory mechanisms of the body. Therefore, it is important to consider the possible effect of the contrast media on the results of laboratory tests when interpreting laboratory test results after the administration of contrast media. The results of laboratory tests after the administration of contrast media may be influenced by the following factors:

- **Changes in renal function:** Changes in renal function may occur after the administration of contrast media. The results of laboratory tests may be affected by the concentration and volume of contrast media administered, as well as by the length of time the contrast media are in contact with the body fluid. In general, the results of laboratory tests that are performed after the administration of contrast media may be more accurate if the patient is well hydrated.

**Drug Interactions**

**Hypertension**

Hypertension has been reported in patients with a history of hypertension or who are on antihypertensive therapy. The use of contrast media may result in changes in the results of laboratory tests that are performed after the administration of contrast media. These changes may be related to the concentration and volume of contrast media administered, to the length of time the contrast media are in contact with the body fluid, and to the effect of the contrast media on the regulatory mechanisms of the body. Therefore, it is important to consider the possible effect of the contrast media on the results of laboratory tests when interpreting laboratory test results after the administration of contrast media. The results of laboratory tests after the administration of contrast media may be influenced by the following factors:

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**DIABETIC PATIENTS**

Diabetic patients may have an increased risk of developing reactions to contrast media. In general, the risk is low and does not depend on the type of diabetes. However, diabetic patients may have a higher risk of developing reactions to contrast media if they have a history of renal failure, hypertension, or heart disease. The use of contrast media may result in changes in the results of laboratory tests that are performed after the administration of contrast media. These changes may be related to the concentration and volume of contrast media administered, to the length of time the contrast media are in contact with the body fluid, and to the effect of the contrast media on the regulatory mechanisms of the body. Therefore, it is important to consider the possible effect of the contrast media on the results of laboratory tests when interpreting laboratory test results after the administration of contrast media. The results of laboratory tests after the administration of contrast media may be influenced by the following factors:

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