**CONTRASTABILITY**

The strategically advantageous choice for enhanced imaging

ISOVUE® (iopamidol injection) covers the 4 characteristics of contrast media that have been recognized as crucial in advancing imaging excellence and patient care.

**01 Excellent Visualization**
Delivers the highest concentration of iodine available in the United States, to maximize visualization.

**02 Dosing Flexibility**
Dosing options allow for convenient use in multiple indications.

**03 Established Safety**
Published studies have shown no statistically significant difference in the incidence of contrast-induced nephropathy (CIN) between the nonionic monomer ISOVUE and the nonionic dimer Visipaque™ (iodixanol injection).

**04 Radiation Reduction**
Meets today’s dose reduction strategies.

**CLINICAL STUDIES DEMONSTRATE SIGNIFICANTLY LOWER RATES OF LATE ADVERSE REACTIONS WITH ISOVUE VS VISIPAQUE**

![Graph showing lower rates of late adverse reactions with ISOVUE vs VISIPAQUE.](image)

Two double-blind studies evaluated the rates of late adverse reactions following administration of iopamidol vs iodixanol in 4109 patients who underwent cardiac catheterization.

In one of the studies, only 4.2% of iopamidol patients experienced itching and skin reactions vs 12.2% of iodixanol patients.

*This chart reflects the difference in percentages of patients who developed skin rashes following discharge from the hospital.

**INDICATIONS AND USAGE**
Isovue is indicated for angiography throughout the cardiovascular system, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, pediatric angiocardiology, selective visceral arteriography and aortography, peripheral venography (phlebography), and adult and pediatric intravenous excretory urography and intravenous adult and pediatric contrast enhancement of computed tomographic (CECT) head and body imaging.

**IMPORTANT SAFETY INFORMATION**
ISOVUE IS NOT FOR INTRATHECAL USE. Iopamidol Injection is available as Isovue-M® for intrathecal administration.

Nonionic iodinated contrast media inhibit blood coagulation, in vitro, less than ionic contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media. Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events.

Caution must be exercised in patients with severely impaired renal function, those with combined renal and hepatic disease, or anuria, particularly when larger and repeat doses are administered. Radiopaque diagnostic contrast agents are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria. Caution should be exercised in hydrating patients with underlying conditions that may be worsened by fluid overload, such as congestive heart failure. Diabetic nephropathy may predispose to acute renal impairment following intravascular contrast media administration. Acute renal impairment following contrast media administration may precipitate lactic acidosis in patients who are taking biguanides. Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with preexisting renal disease). Patients should be well hydrated prior to and following iopamidol administration.

The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions, should always be considered. Patients at increased risk include those with a history of a previous reaction to a contrast medium, patients with a known sensitivity to iodine per se, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies).

Please see accompanying full Prescribing Information.

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Committed to You.

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**ORDERING INFORMATION**

**ISOVUE®-300** (iopamidol injection 61%)

<table>
<thead>
<tr>
<th>Concentration (mgI/mL) of iodine.</th>
<th>Ten 50 mL vials</th>
<th>Ten 75 mL bottles</th>
<th>Ten 100 mL bottles</th>
<th>Ten 150 mL bottles</th>
<th>Ten 200 mL bottles†</th>
<th>Six 500 mL bottles†</th>
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<tr>
<td>NDC No.</td>
<td>0270-1315-25</td>
<td>0270-1315-30</td>
<td>0270-1315-47</td>
<td>0270-1315-35</td>
<td>0270-1315-50</td>
<td>0270-1315-41</td>
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**ISOVUE®-200** (iopamidol injection 41%)

<table>
<thead>
<tr>
<th>Concentration (mgI/mL) of iodine.</th>
<th>Ten 50 mL vials</th>
<th>Ten 200 mL bottles†</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC No.</td>
<td>0270-1314-30</td>
<td>0270-1314-15</td>
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</table>

**ISOVUE®-370** (iopamidol injection 76%)

<table>
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<tr>
<th>Concentration (mgI/mL) of iodine.</th>
<th>Ten 50 mL vials</th>
<th>Ten 75 mL bottles</th>
<th>Ten 100 mL bottles</th>
<th>Ten 125 mL bottles</th>
<th>Ten 150 mL bottles</th>
<th>Ten 200 mL bottles†</th>
<th>Six 500 mL bottles†</th>
</tr>
</thead>
</table>

**ISOVUE®-250** (iopamidol injection 51%)

<table>
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<tr>
<th>Concentration (mgI/mL) of iodine.</th>
<th>Ten 50 mL vials</th>
<th>Ten 75 mL bottles</th>
<th>Ten 100 mL bottles</th>
<th>Ten 150 mL bottles</th>
<th>Ten 200 mL bottles†</th>
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</tr>
</thead>
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<td>NDC No.</td>
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<td>0270-1317-02</td>
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<td>0270-1317-41</td>
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<td>0270-1317-48</td>
</tr>
</tbody>
</table>

**INDICATIONS AND USAGE**

Isovue is indicated for angiography throughout the cardiovascular system, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, pediatric angiography, selective visceral arteriography and aortography, peripheral venography (phlebography), and adult and pediatric intravascular excretory urography and intravenous adult and pediatric contrast enhancement of computed tomographic (CT) head and body imaging.

**IMPORTANT SAFETY INFORMATION**

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The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions, should always be considered. Patients at increased risk include diabetic patients, and in susceptible nondiabetic patients (often elderly with preexisting renal disease). Patients should be well hydrated prior to and following iopamidol administration.

**Please see full accompanying Prescribing Information.**

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**REFERENCES:**

8. Omnique (iobitumumab injection) full Prescribing Information. GE Healthcare; 2010.

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Experience with iopamidol suggests there is much less discomfort (e.g. pain and/or warmth) with peripheral arteriography. Fewer changes are noted in ventricular function after combined procedures has not exceeded 200 mL. EKG monitoring is essential.

Idiosyncratic reactions are subdivided into minor, intermediate, and severe. The minor reactions are self-limited and of short duration; the severe reactions are life-threatening and may uncommonly occur within 2-3 days (range 1-7 days) after the administration of contrast (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS).

Pediatric Excretory Urography

The suggested dose for ISOVUE-250 is 130 to 240 mL and for ISOVUE-300 is 100 to 200 mL by intravenous administration. Imaging may be performed immediately after completion of administration.

Iopamidol Injection is also available as ISOVUE-M (meglumine iopamidol). The suggested dose for single injections in radiographic imaging (intravenous admistration) is 370 mL. For injection into the cranium, the suggested dose is 100 to 200 mL. For injection into the spinal column, the suggested dose is 60 to 100 mL (NDC 0270-1314-90) and 100 mL (NDC 0270-1316-90) respectively. For injection into peripheral arteries, the suggested dose is 15 to 30 mL (NDC 0270-1324-90) and 30 to 60 mL (NDC 0270-1325-90) respectively.

Computed Tomography

ISOVUE-200 (lopamidol Injection 41%) Ten 50 mL single dose vials (NDC 0270-1314-30) Ten 200 mL single dose bottles (NDC 0270-1314-35) Ten 125 mL single dose bottles (NDC 0270-1316-04) Ten 150 mL single dose bottles (NDC 0270-1316-37)

ISOVUE-250 (lopamidol Injection 51%) Ten 50 mL single dose vials (NDC 0270-1314-40) Ten 250 mL single dose bottles (NDC 0270-1314-45) Ten 200 mL single dose bottles (NDC 0270-1316-30) Ten 150 mL single dose bottles (NDC 0270-1316-41) Ten 125 mL single dose bottles (NDC 0270-1316-80)

ISOVUE-300 (lopamidol Injection 61%) Ten 50 mL single dose vials (NDC 0270-1314-50) Ten 250 mL single dose bottles (NDC 0270-1314-55) Ten 250 mL single dose bottles (NDC 0270-1314-35) Ten 150 mL single dose bottles (NDC 0270-1316-53) Ten 125 mL single dose bottles (NDC 0270-1316-90)

ISOVUE-370 (lopamidol Injection 76%) Ten 50 mL single dose vials (NDC 0270-1314-60) Ten 250 mL single dose bottles (NDC 0270-1314-65) Ten 200 mL single dose bottles (NDC 0270-1314-35) Ten 150 mL single dose bottles (NDC 0270-1316-70) Ten 125 mL single dose bottles (NDC 0270-1316-00)

CONTRAINDICATIONS

ISOVUE-200, 250, 300 and 370 are NOT FOR INTRATHECAL USE. See Indications, and Dosage and Administration sections for further details.
**GENERAL ADVERSE REACTIONS**

Intravascular injection of contrast media is frequently associated with the sensation of warmth and pain especially in peripheral arteriography and venography; pain and warmth are usually self-limited and disappear within a few minutes after the injection, but may be prolonged or even delayed (up to 24 hours) and can be severe. These reactions are more frequent and intense in patients with heart disease. They are generally of minor clinical importance and can be treated with bed rest and the administration of analgesics. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells.

**TERATOGENIC EFFECTS**

There are no adequate and well-controlled studies in pregnant women. Use of this drug in pregnant women should be avoided. In the pregnant female, the risk vs. benefits of use should be considered before the injection is performed. If it is used in pregnancy, or if the patient becomes pregnant within 2 months following administration of this drug, the patient should be apprised of the potential hazard to the fetus.

**NURSING MOTHERS**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when iopamidol is administered to a nursing woman.

**DRUG INTERACTIONS**

Renal toxicity has been reported in a few patients with liver dysfunction who were given oral doses of water-soluble contrast media. Patients should be well hydrated prior to and following the procedure. In patients with severe renal impairment or anuria, use of water-soluble contrast media should be avoided. Serum creatinine levels should be monitored during and following the procedure. If necessary, dialysis should be used to reduce the level of contrast media in the blood.

**CONTRAINDICATIONS**

1. Known hypersensitivity to water-soluble contrast media. 
2. Patients with severe renal impairment or anuria. 
3. Patients with a history of a previous reaction to a contrast medium. 
4. Patients with a history of a previous ischemic episode. 
5. Patients with a known sensitivity to iodine per se. 
6. Patients with a history of a previous reaction to a contrast medium. 
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**WARNINGS**

1. Intravenous injection of contrast media is frequently associated with the sensation of warmth and pain especially in peripheral arteriography and venography; pain and warmth are usually self-limited and disappear within a few minutes after the injection, but may be prolonged or even delayed (up to 24 hours) and can be severe. These reactions are more frequent and intense in patients with heart disease. They are generally of minor clinical importance and can be treated with bed rest and the administration of analgesics. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells.

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**ADVERSE REACTIONS**

The use of plastic syringes to inject gases to be reported. Intravascular injection of contrast media is frequently associated with the sensation of warmth and pain especially in peripheral arteriography and venography; pain and warmth are usually self-limited and disappear within a few minutes after the injection, but may be prolonged or even delayed (up to 24 hours) and can be severe. These reactions are more frequent and intense in patients with heart disease. They are generally of minor clinical importance and can be treated with bed rest and the administration of analgesics. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells. In rare cases, severe reactions, such as anaphylactoid shock, may occur; other reactions have been less frequent and usually of moderate intensity, including: hypotension, tachycardia, flushing, headache, dizziness, nausea, vomiting, chills, fever, urticaria, wheezing, dyspnea, chest and limb pain, perioral paresthesia, and occasional allergic manifestations. These reactions may be due to direct irritation of the arterial wall or to the release of vasoactive or allergic mediators from mast cells or other immune cells.

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