Optiray ™ 350 (Ioversol Injection 74%) contains 741 mg of iodine in 3.5 mL of a nonpyrogenic, aqueous solutions intended for intra vascular administration. Ioversol is designated chemically as N,N' -diacetyl-1,4-bis(2-dioctylaminoethoxy)trans-1,2-cyclohexanedicarboxylate. It is a nonionic, low molecular weight, nonhyperosmolar contrast agent.

**DESCRIPTION**

Optiray ™ 350 is indicated for diagnostic radiography and for the enhancement of computed tomographic images of the head and body, and intravenous excretory urography.

**INDICATIONS AND USAGE**

Optiray ™ 350 is indicated for cerebral angiography and peripheral arteriography and venography.

**CONTRAINDICATIONS**

None.

**WARNINGS**

SEVERE ADVERSE EVENTS – INADVERTENT INTRATHECAL ADMINISTRATION

Optiray ™ 320 is indicated in adults for peripheral and coronary arteriography. The use of OPTIRAY 350 is indicated in children for angiocardiography.

Nonionic iodinated contrast media inhibit blood coagulation, in vitro, to a greater extent 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 cerebral, peripheral, and coronary artery occlusion have been reported with these agents. Thromboembolic events have been associated with patients undergoing procedures involving the use of intravascular contrast agents. Clotting occurred in arteries and veins of different anatomical locations. Serum markers of acute myocardial infarction and cerebral infarction were elevated in patients with serious and fatal events. Patients with multiple myeloma or other paraproteinemia, particularly in those with flares of their disease, are potentially hazardous in patients with multiple myeloma. Pretreatment with aspirin is not recommended since this may predispose the patient to precipitation of the myeloma protein.

Children with homozygous sickle cell disease when administered intravascularly. Reports of thyroid storm following the intravascular use of iodinated contrast agents should be avoided.

**ADVERSE REACTIONS**

The following table of incidence of reactions is based upon clinical experience with the use of Optiray™ 350. The percentage of patients experiencing various reactions is not intended to be exact but serves to illustrate the range of reactions that have been observed.

**PRECAUTIONS**

Each milliliter of OPTIRAY 350 (ioversol injection 74%) contains 741 mg of iodine and is the recommended iodine content of 12% to 22% of the administered dose as a bolus. OPTIRAY 350 contains 50 (35%) mg of sodium.

Maximum contrast enhancement in tissue occurs 5-10 minutes after intravenous injection. The concentration of contrast agent in the blood decreases rapidly as the agent is distributed to the extravascular tissue from which it is then cleared. The half-life of the agent in blood is 1-2 minutes.

Each milliliter of OPTIRAY 350 (ioversol injection 64%) contains 641 mg of iodine and is the recommended iodine content of 12% to 22% of the administered dose as a bolus. OPTIRAY 350 contains 24 (39%) mg of sodium.

Tissue enhancement decreases as a function of the radiopacity of the contrast medium, whereas reduction of the viscosity of the blood enhances the hemodynamic efficiency. The degree of density enhancement is directly related to the iodine content in the extravascular compartment of the tissue. The fall in the blood concentration becomes exponential when the blood supply to the extravascular compartment is reached in about 10 minutes; the degree of enhancement is determined by the rate of blood flow and the ability of the extravascular compartment to accept the contrast medium. The degree of enhancement is determined by the rate of blood flow and the ability of the extravascular compartment to accept the contrast medium. The degree of enhancement is determined by the rate of blood flow and the ability of the extravascular compartment to accept the contrast medium. The degree of enhancement is determined by the rate of blood flow and the ability of the extravascular compartment to accept the contrast medium.

**REFERENCES**


**CLINICAL PHARMACOLOGY**

The pharmacokinetics of Optiray™ 350 were studied in normal subjects with an open compartment model with first order elimination in a 60 ± 15 kg female, an open compartment model with first order elimination in a 70 ± 20 kg male, and an open compartment model with first order elimination in a 120 ± 15 kg male. The results are shown in the table below:

<table>
<thead>
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<th>Species</th>
<th>Species</th>
<th>Species</th>
</tr>
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<tbody>
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<td>Human</td>
</tr>
<tr>
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<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Iodine Content (mg I/mL)</td>
<td>Iodine Content (mg I/mL)</td>
<td>Iodine Content (mg I/mL)</td>
</tr>
<tr>
<td>741</td>
<td>641</td>
<td>509</td>
</tr>
</tbody>
</table>

**INDICATIONS AND USAGE**

Optiray ™ 350 is indicated for cerebral angiography and peripheral arteriography and venography.

**CONTRAINDICATIONS**

None.

**WARNINGS**

SEVERE ADVERSE EVENTS – INADVERTENT INTRATHECAL ADMINISTRATION

Optiray ™ 350 is indicated in children for angiocardiography.

**ADVERSE REACTIONS**

The following table of incidence of reactions is based upon clinical experience with the use of Optiray™ 350. The percentage of patients experiencing various reactions is not intended to be exact but serves to illustrate the range of reactions that have been observed.

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OPTIRAY 350 or OPTIRAY 320 is recommended for this procedure. The usual individual injection for visualization of the carotid or vertebral arteries requires 10 to 15 mL. For a simultaneous four vessel study requires 20 to 50 mL. Total procedural doses should not usually exceed 200 mL.

For the RFID Technology to function, the syringe must be used with an active injectable syringe pump, which must be connected to the injector. The RFID tag should have an expected life of up to one month in a contract media warmer environment at or above 70°F (21°C) or up to 60 days in controlled room temperature environment. The RFID tag should not be exposed to temperatures exceeding 110°F (43°C) or a humidity above 100% RH, otherwise the RFID tag may lose functionality. If the RFID tag becomes non-functional, the user will notified. Should this occur the OPTIRAY syringe with the non-functional RFID tag may still be used but no data will be transferred to the injector.

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This information is for Ultima® syringes containing OPTIRAY that have been equipped with an RFID technology. In Ultima® syringes with an RFID, the act of pulling back on the plunger will activate the RFID chip and provide the injectable syringe pump with a delivery value. The RFID chip may only be activated once per plunger pull. The RFID chip will not function if the plunger is repositioned after the first pull. This information is for Ultima® syringes containing OPTIRAY that have been equipped with an RFID technology. In Ultima® syringes with an RFID, the act of pulling back on the plunger will activate the RFID chip and provide the injectable syringe pump with a delivery value. The RFID chip may only be activated once per plunger pull. The RFID chip will not function if the plunger is repositioned after the first pull. This information is for Ultima® syringes containing OPTIRAY that have been equipped with an RFID technology. In Ultima® syringes with an RFID, the act of pulling back on the plunger will activate the RFID chip and provide the injectable syringe pump with a delivery value. The RFID chip may only be activated once per plunger pull. The RFID chip will not function if the plunger is repositioned after the first pull.