Optiray (ioversol injection) formulations are sterile, nonpyrogenic, aqueous solutions of ioversol containing 64%, 68%, and 74% (w/v) ioversol (a nonionic, water-soluble, ioanikos, macrocyclic, nonionic, nonradioactive iodine-containing contrast material). Ioversol is chemically designated as C34H48I4N8O8S4. Ioversol contains an average of 47.2% free organic iodine content on a molar basis. Ioversol is nonionic and does not dissociate in solution. The molecular weight of ioversol is 807.11 and the organically bound iodine (mg/mL)

**WARNINGS**

**SAFETY AND ADVERSE EVENTS - MALIGNANCY/INTERTHELAL ADMINISTRATION: Ioversol injection is contraindicated in children.** Adverse reactions have been reported following intrathecal administration. These adverse reactions include irritative symptoms of the nervous system, including convulsions, headache, cerebral infarct, and death. The exact mechanism of these adverse reactions is not known. Convulsions have been reported in patients receiving intrathecal injections of ioversol. The reported convulsions have occurred within 2 to 30 minutes after cessation of injection and have been associated with severe hypertension or hypertension. The pattern of adverse reactions was similar in patients receiving intrathecal injections of ioversol 320, 240, and 120. The convulsions were reported to be malignant, benign, or normal tissue, but would probably not be a cyst, tumor, abscess, arteriovenous malformation, or other neoplastic formation. Because convulsive seizures may provide adequate diagnostic information in the individual patient, the decision to employ contrast enhancement, which may be necessary in patients receiving intrathecal ioversol, must be made after careful examination of the patient's condition and consideration of the possible benefits of enhanced radiographic visualization. Contrast enhancement is not indicated in patients with known intracranial neoplasm, cerebrovascular disease, severe arterial or venous disease, or other condition which may predispose the patient to increased intracranial pressure. Contrast enhancement should not be performed in patients with severe aortic stenosis, severe mitral stenosis, severe mitral regurgitation, or severe aortic regurgitation. Caution must be exercised in patients with severely impaired renal function, severe pulmonary hypertension, severe hypotension, severe hypovolemia, or septicemia. Because convulsions may affect the ability of patients to pass urine, the patient should be monitored for urinary retention following such seizures. Other drugs should not be mixed with ioversol injection.

**PRECAUTIONS:**

**Environmental Considerations: Ioversol injection is sterile, nonpyrogenic, aqueous solutions of ioversol containing 64%, 68%, and 74% (w/v) ioversol (a nonionic, water-soluble, ioanikos, macrocyclic, nonionic, nonradioactive iodine-containing contrast material). Ioversol contains an average of 47.2% free organic iodine content on a molar basis. Ioversol is nonionic and does not dissociate in solution. The molecular weight of ioversol is 807.11 and the organically bound iodine content (mg/mL) solutions intended for intravascular administration as diagnostic radiopaque agents and, in contrast enhanced computed tomographic body imaging (nonneural structures). Ioversol injection is contraindicated in children for angiographic and venographic procedures, to aorta and/or iliac arteries, spine arteriography, spinal arteriography, and renal arteriography. Venography, aortography, and left ventriculography.

**Contraindications:** Ioversol injection is contraindicated in children for angiographic and venographic procedures, to aorta and/or iliac arteries, spine arteriography, spinal arteriography, and renal arteriography. Venography, aortography, and left ventriculography. Ioversol injection should not be used to fill or prime any type of venous or arterial catheter system or tubing because of the risk of arterial or venous occlusion. Ioversol injection should not be used to fill or prime any type of venous or arterial catheter system or tubing because of the risk of arterial or venous occlusion. Ioversol injection is contraindicated in children for angiographic and venographic procedures, to aorta and/or iliac arteries, spine arteriography, spinal arteriography, and renal arteriography. Venography, aortography, and left ventriculography. Ioversol injection should not be used to fill or prime any type of venous or arterial catheter system or tubing because of the risk of arterial or venous occlusion. Ioversol injection is contraindicated in children for angiographic and venographic procedures, to aorta and/or iliac arteries, spine arteriography, spinal arteriography, and renal arteriography. Venography, aortography, and left ventriculography. Ioversol injection should not be used to fill or prime any type of venous or arterial catheter system or tubing because of the risk of arterial or venous occlusion.
Patients should be well hydrated prior to and following Optiray (ioversol at or close to body temperature when injected. Such as anticipated pathology, degree and extent of opacification required, size of the vessel and the rate of blood flow within the vessel. Other factors carefully individualized accounting for factors such as age, body weight, the possibility of an adverse reaction. Most procedures do not require use obtain adequate visualization should be used. A lower dose may reduce changes in hepatorenal chemistry tests. Arterial thrombosis, displacement of consciousness, coma, severe cardiovascular disturbances and death. Contrast agents and are possible with any water soluble, iodinated contrast media. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions. Adverse reactions to injectable contrast media fall into two categories: chemotoxic reactions and idiosyncratic reactions.

**INDICATIONS, USAGE AND PROCEDURAL INFORMATION**

**GENERAL ANGIOGRAPHY**

- Ioversol is useful for intravascular injection into the arterial system as well as intravenous administration. 
- Ioversol is used to produce contrast on the arterial and venous phases of angiography. 
- It provides excellent opacification of the arterial system and allows visualization of intravascular structures. 
- Ioversol is also used for selective angiography, including catheterization of the ascending aorta, femoral, iliac arteries; and the arteries of the extremities.

**Non-neoplastic Conditions**

- Ioversol is recommended for use in children for most non neoplastic conditions. 
- The dosage recommended for use in children is 1 mL/kg to 3 mL/kg of body weight for pediatric patients weighing less than 10 kg. 
- For children weighing 10 kg or more, the dosage should not exceed 3 mL/kg.

**INTRAVASCULAR DIGITAL SUBTRACTION ANGIOGRAPHY**

- Intravenous digital subtraction angiography (IVDSA) is a subtractive technique used to acquire real-time subtraction images of the arterial system following intravenous injection of iodinated contrast media. 
- IVDSA allows for rapid examination of the arterial system and provides high-quality images of the vascular anatomy.

**Dosage and Administration**

- Optiray 350, Optiray 320, Optiray 300 or Optiray 240 may be administered by intravenous injection by a combination of the usual doses are summarized below:

**Adverse Reactions**

- There are no cardiovascular system reactions with Optiray or controlled injection rates. 
- Minor side effects may include flushing, pruritus, chest pain, and hemodynamic disturbances.

**CONTRAINDICATIONS**

- Ioversol is contraindicated in patients with a history of a previous reaction to Ioversol.

**WARNINGS**

- Patients should be well hydrated prior to and following Optiray injection

**Adverse Reactions**

- There are no cardiovascular system reactions with Optiray or controlled injection rates. Minor side effects may include flushing, pruritus, chest pain, and hemodynamic disturbances.

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**WARNINGS**

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