**Optiray® (ioversol injection)**

**DESCRIPTION**

Optiray® (ioversol injection) is a radiopaque, nonionic, low osmolar, low viscosity, and low protein binding contrast medium for intravascular or extravascular radiographic use. It is supplied in the form of a 300 mg/mL solution, 320 mg/mL solution, and 350 mg/mL solution. The specific gravity of the solution ranges from 1.14 to 1.16.

**INDICATIONS AND USAGE**

Optiray® 350 is indicated for pediatric and non-vascular computed tomography of the head and body. Optiray® 320 is indicated for pediatric and non-vascular computed tomography of the head and body, and angiography. Optiray® 300 is indicated for intravenous radiographic examinations that require high-density imaging, such as the following:

1. **CT SCANNING OF THE HEAD**
   - To improve visualization of normal and pathological conditions of the brain, cranial and para-cranial structures, craniofacial structures, and the extracranial structures.
   - To improve visualization of intracranial lesions, tumors, and aneurysms.
   - To improve visualization of extracranial structures, such as the sinuses, orbits, and paranasal structures.
   - To improve visualization of dural sinus, venous sinuses, and extracranial vessels.

2. **Angiography**
   - To improve visualization of interventional radiographic procedures, such as angioplasty, stent placement, and embolization.

3. **Vascular Imaging**
   - To improve visualization of the vascular system, such as the aorta, iliac arteries, and peripheral arteries.

4. **Urography**
   - To improve visualization of the urinary system, such as the kidneys, ureters, and bladder.

5. **Gastrointestinal Imaging**
   - To improve visualization of the gastrointestinal tract, such as the stomach, small intestine, and colon.

6. **Cardiography**
   - To improve visualization of the cardiac structures, such as the heart, coronary arteries, and pericardium.

Optiray® 350 is also indicated for contrast enhanced computed tomographic imaging of the head and body, and for angiography. Optiray® 320 is also indicated for contrast enhanced computed tomographic imaging of the head and body, and for angiography. Optiray® 300 is indicated for intravenous radiographic examinations that require high-density imaging, such as the following:

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**ADVERSE REACTIONS**

The following adverse reactions are associated with the use of Optiray® (ioversol injection) in clinical studies and are listed in approximate order of frequency:

1. **Skin Reactions**
   - Rash, urticaria, angioedema, pruritus, erythema multiforme, morbilliform rash, and Stevens-Johnson syndrome.
   - Pain, burning, tenderness, or swelling at the injection site.

2. **Respiratory Reactions**
   - Shortness of breath, coughing, wheezing, dyspnea, and asthma-like symptoms.

3. **Gastrointestinal Reactions**
   - Nausea, vomiting, abdominal pain, diarrhea, and constipation.

4. **Central Nervous System Reactions**
   - Headache, dizziness, vertigo, tinnitus, and syncope.

5. **Other Reactions**
   - Hemolysis, thrombocytopenia, anaphylactic reactions, and allergic reactions.
   - Fever, chills, myalgia, arthralgia, and flu-like symptoms.

**CONTRAINDICATIONS**

Optiray® (ioversol injection) is contraindicated in patients with known hypersensitivity to the radiopaque contrast agent, to the preservatives, or to the inactive ingredients of the product.

**PRECAUTIONS**

1. **Renal Function**
   - Patients with impaired renal function may be at increased risk of contrast-induced nephropathy. Close monitoring of renal function is recommended in patients with pre-existing renal disease.

2. **Cardiac Function**
   - Patients with unstable or acute coronary syndromes may be at increased risk of contrast-induced myocardial ischemia. Close monitoring of cardiac function is recommended in these patients.

3. **Hypertensive Crisis**
   - Patients with a history of hypertension or who are prone to develop hypertensive crisis during radiographic procedures should be monitored closely.

4. **Pregnancy**
   - Women of childbearing age should be advised of the potential risks to the fetus if the procedure is performed during pregnancy.

5. **Breastfeeding**
   - The safety of breastfeeding while using Optiray® (ioversol injection) has not been studied.

6. **Pediatric Use**
   - The safety and efficacy of Optiray® (ioversol injection) in children have not been established.

**NURSING MOTHERS**

Optiray® (ioversol injection) is excreted in human milk. The clinical relevance of this finding is unknown.

**DRUG INTERACTIONS**

Optiray® (ioversol injection) is not expected to have significant drug interactions.

**OVERDOSAGE**

Overdosage of Optiray® (ioversol injection) is unlikely to be of clinical significance. However, if overdosage occurs, supportive measures should be initiated to manage any untoward reactions that may occur.

**PEDIATRIC USE**

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   - Hemolysis, thrombocytopenia, anaphylactic reactions, and allergic reactions.
   - Fever, chills, myalgia, arthralgia, and flu-like symptoms.
Manditory prerequisites to the procedure are attack, laryngospasm and bronchospasm, apnea and cyanosis. Rarely and tissue necrosis. Usually transient but may be permanent, coma and death.

Idiosyncratic reactions are with a history of allergy is twice that of the general population. Patients with general pain shaking chills.

Cardiovascular: Nervous:

Pulsation should be present in the artery to be injected. In thromboangiitis obliterans, or ascending infection associated with a totally obstructed venous system. In order to flow of the vessel being injected.

Dosage and Administration:

OPTRAY is supplied in single dose containers. Discard any unused portion of solution. Discard any unused portion of OPTRAY in a puncture resistant container. Do not return unused portions to the main supply. Discard any unused portions of OPTRAY in a puncture resistant container. Do not return unused portions to the main supply.

NOTE: Prior to injection, reconstitute each vial with 10 mL of Sterile Water or 0.9% Sterile Sodium Chloride Injection. Make up a dose immediately before injection. Reconstituted OPTRAY is stable for 4 hours at room temperature. Avoid excessive dilution. Do not use reconstituted OPTRAY for administration into the eye. Reconstituted OPTRAY is stable for 4 hours at room temperature. Avoid excessive dilution. Do not use reconstituted OPTRAY for administration into the eye. Reconstituted OPTRAY is stable for 4 hours at room temperature. Avoid excessive dilution. Do not use reconstituted OPTRAY for administration into the eye. Reconstituted OPTRAY is stable for 4 hours at room temperature. Avoid excessive dilution. Do not use reconstituted OPTRAY for administration into the eye. Reconstituted OPTRAY is stable for 4 hours at room temperature. Avoid excessive dilution. Do not use reconstituted OPTRAY for administration into the eye.