Optiray® 350 (IOVERSOL INJECTION 74%) Optiray® 320 (IOVERSOL INJECTION 68%) Optiray® 300 (IOVERSOL INJECTION 64%) Optiray® 240 (IOVERSOL INJECTION 51%) 

**WARNINGS**

SEVERE ADVERSE EVENTS — INADVERTENT INTRATHECAL ADMINISTRATION: Various adverse reactions have been reported following the inadvertent intrathecal administration of iodinated contrast media. These reactions can be severe and include meningitis, meningoencephalitis, meningoencephalocele, ischemia, necrosis, and radiculopathy. They may also be fatal. The clinical presentation can include fever, chills, headache, neck stiffness, cranial nerve palsies, seizures, and death. Additional symptoms may include back pain, neck pain, and motor weakness. These reactions can be delayed, and it is important to continue to monitor patients for signs of neurological impairment following contrast administration. Intralesional injection of iodinated contrast media into the epidural space (intrathecal) has also been reported, leading to adverse neurological events. These events can occur due to the physical properties of the contrast media, such as their viscosity and solubility. Therefore, it is crucial to ensure proper injection technique and to monitor patients for signs of neurological impairment.

**GENERAL INFORMATION**

**CONTRAINDICATIONS**

None.

**ADVERSE REACTIONS**

The most common adverse reactions reported with Optiray® include headache, nausea, vomiting, diarrhea, and abdominal pain. These effects are usually mild and transient. Less common reactions include rash, pruritus, urticaria, and anaphylactic reactions. In some cases, these reactions may be severe and require immediate medical attention. For instance, patients may experience shortness of breath, wheezing, coughing, and a feeling of impending doom. In these situations, the patient should be administered high-dose steroids and intravenous fluids immediately. Other reactions may include hypotension, tachycardia, and atrial fibrillation. In severe cases, the patient may require vasopressors and inotropic support. In the worst-case scenario, cardiopulmonary resuscitation may be necessary. Patients should be observed for a minimum of 1-2 hours following the administration of Optiray® to monitor for any adverse reactions. If any adverse reactions occur, they should be managed according to established guidelines. The patient should be kept under close medical supervision and observed for any signs of deterioration. In the event of an adverse reaction, the patient should be treated as per standard hospital procedures, and the incident should be reported to regulatory authorities and the manufacturer. Proper patient education and informed consent are essential to minimize the risk of adverse reactions. The patient should be reviewed for any underlying medical conditions and allergies prior to the procedure. The patient should be informed of the potential risks and benefits of the procedure and given the opportunity to provide informed consent. If any adverse reactions occur, they should be managed according to established guidelines. The patient should be kept under close medical supervision and observed for any signs of deterioration. In the event of an adverse reaction, the patient should be treated as per standard hospital procedures, and the incident should be reported to regulatory authorities and the manufacturer. Proper patient education and informed consent are essential to minimize the risk of adverse reactions. The patient should be reviewed for any underlying medical conditions and allergies prior to the procedure. The patient should be informed of the potential risks and benefits of the procedure and given the opportunity to provide informed consent. If any adverse reactions occur, they should be managed according to established guidelines. The patient should be kept under close medical supervision and observed for any signs of deterioration. In the event of an adverse reaction, the patient should be treated as per standard hospital procedures, and the incident should be reported to regulatory authorities and the manufacturer. Proper patient education and informed consent are essential to minimize the risk of adverse reactions. The patient should be reviewed for any underlying medical conditions and allergies prior to the procedure. The patient should be informed of the potential risks and benefits of the procedure and given the opportunity to provide informed consent.
If during administration a reaction occurs, the injection should be stopped until the reaction has subsided. Patients should be well hydrated prior to and following D I O T R E N A P Y administration or other medications. As an aid in oral therapy, other drugs should not be mixed with D I O T R E N A P Y solutions. When D I O T R E N A P Y is administered, it should be administered in proportion to age and body weight. The total administered dose should not exceed 3 mL/kg.

Sterile technique must be used in all vascular injections involving contrast media. As with all radiopaque contrast agents, only the lowest dose necessary to obtain adequate visualization should be used. A lower dose may reduce the possibility of an adverse reaction. Most patients receive 2 mL/kg of D I O T R E N A P Y for this procedure. The usual individual injection for visualization of the carotid or vertebral arteries is 2 to 3 mL. For a simultaneous four vessel study requires 20 to 50 mL. Total procedural doses should not usually exceed 200 mL. As with all radiopaque contrast agents, when necessary, the agent should be at or close to body temperature when injected.

Arteriovenous malformations and aneurysms will show contrast enhancement. For these vascular lesions the enhancement is probably dependent on the iodine content of the circulating blood in the feeding vessels, while for contrast media administration may be helpful in ruling out the possibility of associated arterio venous malformation.

OPTIRAY 320 is recommended for visceral angiography (e.g., angiography of visceral arteries in patients with advanced arteriosclerosis, severe hypertension, or advanced arteriosclerosis). The usual dose is 50 to 150 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 100 to 250 mL of OPTIRAY 240. Scanning may be performed after 2 to 4 minutes if the liver is in the field of view. The dose should not exceed 150 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 250 mL of OPTIRAY 240.

OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 may be administered by bolus injection, by rapid infusion, or by a combination of both. The usual doses are summarized below:

- OPTIRAY 350: 25 to 75 mL, 50 to 150 mL
- OPTIRAY 320: 25 to 75 mL, 50 to 150 mL
- OPTIRAY 300: 25 to 75 mL, 50 to 150 mL
- OPTIRAY 240: 35 to 100 mL, 70 to 200 mL

These doses may be repeated as necessary. Total procedural doses for the combined procedures should not usually exceed 250 mL. When large volumes are administered, as in venography and angiography, it has been suggested that severe reactions may be prevented with a speed of injection of 100 to 200 mL per minute. When large volumes are administered, as in venography and angiography, it has been suggested that severe reactions may be prevented with a speed of injection of 100 to 200 mL per minute.