Mallinckrodt Pharmaceuticals

Optiray™ 240 (ioversol injection 51%)

This information is intended for U.S. healthcare professionals only.

Optiray 240 contrast agent is lower osmolar, lower viscosity and nonionic. Since 1989, over 140 million doses of Optiray contrast agent (all concentrations combined) have been sold. It has a well known safety profile, and a broad range of indications. Optiray 240 contrast agent is available in Ultraject™ prefilled syringes, click here to learn more. A large number of packaging configurations in syringes, vials and bottles provides a number of choices to meet your individual patient needs.

Optiray 240 contrast agent is injectable and intended for intravascular administration. It is a prescription drug that is intended to be therapeutically and biologically inert when injected into the body for use in organ or tissue enhancement in computed tomography, X-ray and fluoroscopy imaging procedures for which it is approved. Each milliliter of Optiray 240 contrast agent contains 509 mg of ioversol, 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer.

INDICATIONS AND USAGE

Optiray 240 (ioversol injection 51%) is indicated for cerebral angiography and venography, tomographic imaging of the head and body and intravenous excretory urography.

IMPORTANT RISK INFORMATION

NOT FOR INTRATHECAL USE

WARNINGS AND PRECAUTIONS

- 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.
- Serious or fatal reactions have been associated with the administration of iodine-containing radiopaque media. It is of utmost importance to be completely prepared to treat any contrast medium reaction.
- As with any contrast medium, serious neurologic sequelae, including permanent paralysis, can occur following cerebral arteriography, selective spinal arteriography and arteriography of vessels supplying the spinal cord.
- Caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, severe thyrotoxicosis, myelomatosis, or anuria, particularly when large doses are administered.
- Intravascularly administered iodine-containing radiopaque media are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria.
- Administration of radiopaque materials to patients known or suspected of having pheochromocytoma should be performed with extreme caution.
- Contrast media may promote sickling in individuals who are homozygous for sickle cell disease when administered intravascularly.
- Reports of thyroid storm following the intravascular use of iodinated radiopaque agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule.
- Preparatory dehydration is dangerous and may contribute to acute renal failure. Patients should be well hydrated prior to and following the administration of Optiray.

- Severe reactions to contrast media, including serious anaphylactoid and cardiovascular reactions, are possible. A positive history of bronchial asthma or allergy (including food), a family history of allergy, or a previous reaction or hypersensitivity to a contrast agent may imply a greater than usual risk.
- A higher incidence of adverse reactions has been reported for patients who receive general anesthesia.
- Angiography should be avoided whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.
- Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed hemodynamic disturbances.

ADVERSE REACTIONS

- Serious adverse reactions include laryngospasm, bronchospasm, cyanosis, apnea, cardiac arrest, shock, and hemodynamic collapse.
- Common adverse reactions include a feeling of warmth or pain.

USE IN SPECIFIC POPULATIONS

- Pediatrics: Safety and effectiveness in children has not been established for Optiray 240.
- Breast feeding: It is not known whether ioversol is excreted in human milk.

Ordering Information

Description	Qty	Unit	Size	Order #	11 Digit NDC
Bottle	25	each	50 mL	132406	00019132406
Bottle	12	each	100 mL	132411	00019132411
Bottle	12	each	150 mL	132416	00019132416
Bottle	12	each	200 mL	132421	00019132421