



Conray™ (iothalamate meglumine injection USP 60%)

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

Conray contrast agent is injectable, ionic and high osmolar. It is a prescription drug that is therapeutically and biologically inert when injected into the body for use in organ or tissue enhancement in certain computed tomography, X-ray and fluoroscopy imaging procedures for which it is approved. Each mL contains 600 mg of iothalamate meglumine, 0.09 mg edetate calcium disodium as a stabilizer and 0.125 mg of monobasic sodium phosphate as a buffer. The solution provides 28.2% (282mg/mL) organically bound iodine. It is available in glass bottles and vials in a variety of fill sizes.

INDICATIONS AND USAGE

Conray (iothalamate meglumine injection USP 60%) is indicated for use in:

- excretory urography
- cerebral angiography
- peripheral arteriography
- venography
- arthrography
- direct cholangiography
- endoscopic retrograde cholangiopancreatography
- contrast enhancement of computed tomographic brain images
- cranial computerized angiotomography
- intravenous digital subtraction angiography
- arterial digital subtraction angiography.
- enhancement of computed tomographic scans performed for detection and evaluation of lesions in the liver, pancreas, kidneys, abdominal aorta, mediastinum, abdominal cavity and retroperitoneal space

IMPORTANT RISK INFORMATION

NOT FOR INTRATHECAL USE

CONTRAINDICATIONS

- Conray is contraindicated in:
 - Use for myelography.
 - Use for Arthrography when infection is present in or near the joint.
 - Use for percutaneous transhepatic cholangiography in patients with coagulation defects and prolonged prothrombin times.
 - Use for endoscopic retrograde cholangiopancreatography during an acute attack of pancreatitis or during severe clinically evident cholangitis and in patients in whom endoscopy is prohibited.

WARNINGS AND PRECAUTIONS

- The possibility of idiosyncratic reaction in susceptible patients should always be considered especially in patients with

allergies or hypersensitivity to contrast media or iodine.

- Ionic iodinated contrast media inhibit blood coagulation, in vitro, more than nonionic contrast media. Nonetheless, it is prudent to avoid prolonged contact of blood with syringes containing ionic 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.
- A rare association between contrast administration and clinical deterioration, including convulsions and death, has been reported in patients with subarachnoid hemorrhage.
- A definite risk exists in the use of intravascular contrast agents in patients who are known to have multiple myeloma. In such instances, there has been anuria resulting in progressive uremia, renal failure and eventually death.
- Administration of radiopaque materials to patients known or suspected to have pheochromocytoma should be performed with extreme caution.
- Contrast media have been shown to promote the phenomenon of sickling in individuals who are homozygous for sickle cell disease when the material is injected intravenously or intraarterially.
- Convulsions have occurred in patients with primary or metastatic cerebral lesions following the administration of iodine-containing radiopaque media for the contrast enhancement of CT brain images.
- Those patients with renal disease are at risk of impaired excretion of the medium. Hydration is necessary in all patients, especially those with renal dysfunction.
- Caution should be exercised in performing contrast medium studies in patients with endotoxemia and/or those with elevated body temperatures.
- The use of IV iodinated radiopaque agents may increase the risk of thyroid storm in patients with hyperthyroidism or autonomously functioning thyroid nodule.
- Angiography should be avoided whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

ADVERSE REACTIONS

- Serious events may include severe cardiovascular responses include rare cases of hypotensive shock, coronary insufficiency, cardiac arrhythmia, fibrillation and arrest.
- The most frequent adverse reactions are nausea, vomiting, facial flush and a feeling of body warmth.

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of Conray for infusion urography have not been established in children under 12 years of age.
- Caution in patients with impaired renal excretion (elderly and diabetic patients may be at risk).

Ordering Information

Description	Qty	Unit	Size	Order #	11 Digit NDC
Bottle	12	each	150 mL	095311	00019095311