

Visican

IODIXANOL

Compositions:

Visican injection: Each 1 ml contains Iodixanol USP 652 mg (equivalent to 320 mg of organically bound iodine).

Pharmacology:

General Iodixanol is a dimeric, isosmolar, nonionic, water soluble, and Iodinated x-ray contrast agent for intravascular administration. Intravascular injection of Iodixanol opacifies those vessels in the path of flow of the contrast agent, permitting radiographic visualization of the internal structures until significant dilution and elimination occurs. Pharmacokinetics: Distribution In an in vitro human plasma study, Iodixanol did not bind to protein. The volume of distribution was 0.26 likely body weight, consistent with distribution to extracellular space. Metabolism Iodixanol metabolites have not been demonstrated. Excretion Plasma and urine levels suggest that body clearance of Iodixanol is primarily due to renal clearance. In adults, approximately 97% of the injected dose of Iodixanol is excreted unchanged in urine within 24 hours, with less than 2% excreted in feces within five days post-injection Pharmacodynamics: As with other iodinated contrast agents, following administration of Visican Injection, the degree of enhancement is directly related to the iodine content in an administered dose; peak iodine plasma levels occur immediately following rapid intravascular injection. Iodine plasma levels fall rapidly within 5 to 10 minutes. This can be accounted for by the dilution in the vascular and extravascular fluid compartments.

Dosage And Administration:

Adult Dosage: Intra-arterial use: (Concentration 270/320 mg I/ml) Arteriographies: 5-10 ml per inj. Selective cerebral: 40-60 ml per inj. Aortography peripheral: 30-60 ml per inj. Angiocardiology: (Concentration 320 mg I/ml) Left ventricle and aortic root: 30-60 ml per inj. Selective coronary arteriography: 4-8 ml per inj. Intravenous use: (Concentration 270/320 mg I/ml) Urography CT-enhancement: 40-80 ml CT of the body: 50-150 ml CT of the head: 75-150 ml Paediatric Dosage: Intra-arterial use: (Concentration 320 mg I/ml) Cardioangiography: 1-2 ml/kg with max recommended dose of 10 ml/kg. All doses depending on age, weight and pathology. Intravenous use: (Concentration 270/320 mg I/ml) Urography Children <7: kg 2-3 ml/kg up to 50 ml (in a few cases up to 150 ml may be given) Children >7: kg 2-3 ml/kg up to 50 ml (in a few cases up to 150 ml may be given) CT-enhancement: (Concentration 270/320 mg I/ml) CT of the body & Body: 2-3 ml/kg up to 50 ml (in a few cases up to 150 ml may be given) Upper Gastrointestinal Studies Children: (Concentration 320 mg I/ml) the dosage must be adjusted individually to allow optimal visualization 5 ml/kg b.w. 10-240 ml has been studied.

Contraindications:

Visican Injection is not indicated for intrathecal use. In the pediatric population prolonged fasting and the administration of a laxative before Visican injection are contraindicated.

Warning And Precaution:

Precautions for use of non-ionic contrast media in general: The risk of serious reactions in connection with use of Visican is regarded as minor. However, iodinated contrast media may provoke anaphylactoid reactions or other manifestations of hypersensitivity. A course of action should therefore be planned in advance, with necessary drugs and equipment available for immediate treatment, should a serious reaction occur. It is advisable always to use an indwelling cannula or catheter for quick intravenous access throughout the entire X-ray procedure. As with other iodinated contrast agents, the use of Visican injection contrast

enhancement may obscure some lesions which are seen on previously unenhanced CT scans. In patients with normal blood-brain barriers and renal failure, iodinated contrast agents have been associated with blood-brain barrier disruption and accumulation of contrast in the brain. Enhancement of the inferior vermis following contrast agent administration has resulted in false positive diagnosis. Hydration Patients should be well hydrated prior to, and following, administration of any contrast medium, including Visican, in order to prevent from acute renal failure. This applies especially to patients with multiple myeloma, diabetes mellitus, renal dysfunction and elderly patients. Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with pre-existing renal insufficiency, diabetes or advanced vascular disease. It is believed that overnight fluid restriction prior to excretory urography generally does not provide better visualization in normal patients. To avoid contrast induced nephropathy, the following should be considered: • Identification of high risk patients • Ensuring adequate hydration. The patient should be hydrated (e.g. at least 100 ml per hour of soft drinks or intravenous saline up to 24 hours after contrast medium administration. In warm areas more fluid should be given). • If necessary by maintaining an i.v. infusion from before the procedure until the contrast medium has been cleared by the kidneys. • Avoiding additional strain on the kidneys in the form of nephrotoxic drugs, oral cholecystography agents, arterial clamping, renal arterial angioplasty, or major surgery, until the contrast medium has been cleared. • Postponing a repeat contrast medium examination until renal function returns to preexamination levels. • Monitor renal function (serum creatinine), serum lactic acid and pH of blood. • Look for symptoms of lactic acidosis (vomiting, somnolence, nausea, epigastric pain, anorexia, hyperpnea, lethargy, diarrhoea and thirst). Blood test results indicative of lactic acidosis: p11-(7-.25 and lactic acid > 5-mmor.

Side Effects:

Most common adverse reactions (incidence greater than 0.5%) in adult patients after Iodixanol injection: Discomfort, warmth, pain. Cardiovascular: angina. Gastrointestinal: diarrhea, nausea, vomiting. Nervous System: agitation, anxiety, insomnia, nervousness, dizziness, headache, migraine, unusual skin sensations, sensory disturbance, fainting, sensation of spinning. Skin: itchy rash, severe itching, hives. Special Senses: Smell, taste, and vision alteration. Pediatric patients experienced similar adverse reactions.

Use in Pregnancy and Lactation:

Pregnancy: There are no data with Iodixanol use in pregnant women to inform any drug-associated risks. Lactation: A lactating woman may pump and discard breast milk for 10 hours after Iodixanol administration.

Drug Interaction:

• Metformin: In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin induced lactic acidosis, possibly as a result of worsening renal function. Stop metformin at the time of, or prior to, Visican administration in patients with an eGFR between 30 and 60 ml/min/1.73 m²; in patients with a history of hepatic impairment, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure, and reinstitute metformin only after renal function is stable. • Radioactive Iodine: Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for 6-8 weeks. • Beta-adrenergic Blocking Agents: The use of beta-adrenergic blocking agents lowers the threshold for and increases the severity of contrast reactions, and reduces the responsiveness of treatment of hypersensitivity reactions with epinephrine. Because of the risk of hypersensitivity reactions, use caution when administering Visican to patients taking

beta-blockers. Oral Cholecystographic Contrast Agents Renal toxicity has been reported in patients with liver dysfunction who were given an oral cholecystographic agent followed by intravascular iodinated contrast agents. Postpone the administration of Visican in patients who have recently received an oral cholecystographic contrast agent Drug Laboratory Test Interactions

Overdosage:

The adverse effects of over dosage of any contrast agent may be life-threatening and affect mainly the pulmonary and cardiovascular systems. Treatment of an over dosage is directed toward the support of all vital functions and prompt institution of symptomatic therapy. Iodixanol Injection does not bind to plasma or serum protein and can be dialyzed.

Storage:

Store at controlled room temperature (not exceeding 30° C). Protect from light. Do not freeze. The bottle, once opened, to be used immediately. Any residue of contrast medium must be discarded.

Packing:

Visican 320 Injection: Each pack contains 1 vial of Visican 320 Injection 50 ml.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.