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℞ Iohexol Injection USP 350mg I/mL.

For the use of Registered Medical Practitioner, or a Hospital or a Laboratory.

AMERICAN

Radioxol 350

Injection

Composition :
Each mL. Contains :
Iohexol USP.....755 mg.
(eq. Organically bound Iodine.....350mg)
Tromethamine USP.....1.21 mg.
Edetate Calcium Disodium USP.....0.1 mg.
Water for Injection IP.....q.s.

Pharmaceutical form
A clear, colourless to pale yellow, sterile aqueous solutions.
Small volume Injection.
100 ml filled in Clear Glass Vial

Therapeutic indications
Iohexol injection is a sterile, pyrogen-free, colorless to pale-yellow solution, in the iodine concentrations contains 755 mg of iohexol equivalent to 350mg of organic iodine per mL Injection is sterilized by autoclaving and contain no preservatives. Unused portions must be discarded. Iohexol solution is sensitive to light and therefore should be protected from exposure.

X-ray contrast medium for use in adults and children for cardioangiography, arteriography, urography, phlebography and CT-enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract..

Contraindications
Hypersensitivity to the active substance or to any of the excipients. Manifest thyrotoxicosis.

Warnings -General
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.

Iohexol Injection USP 350mg I/mL should be used with extreme care in patients with severe functional disturbances of the liver and kidneys, severe thyrotoxicosis, or myelomatosis. Diabetics with a serum creatinine level above 3 mg/dL should not be examined unless the possible benefits of the examination clearly outweigh the additional risk.

Iohexol Injection USP 350mg I/mL is not recommended for use in patients with anuria.

Iohexol Injection USP 350mg I/mL should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is present, do not use.
Information for Patients
Patients receiving injectable radiopaque diagnostic agents should be instructed to:

- Inform your physician if you are pregnant.
- Inform your physician if you are diabetic or if you have multiple myeloma, pheochromocytoma, homozygous sickle cell disease, or known thyroid disorder.
- Inform your physician if you are allergic to any drugs, food, or if you had any reactions to previous injections of dyes used for x-ray procedures.
- Inform your physician about any other medications you are currently taking, including non-prescription drugs, before you are administered this drug.
- Advise patients to inform their physician if they develop a rash after receiving Iohexol Injection USP 350mg I/mL.
- Advise parents/caregivers about the risk of developing thyroid dysfunction after Iohexol Injection USP 350mg I/mL administration.
- Advise parents/caregivers about when to seek medical care for their child to monitor for thyroid function.

Adverse Reactions: Intravascular-General
Serious, life-threatening and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast media, including Iohexol Injection USP 350mg I/mL. The injection of contrast media is frequently associated with the sensation of warmth and pain, especially in peripheral angiography; pain and warmth are less frequent and less severe with Iohexol Injection USP 350mg I/mL than with many contrast media. *Cardiovascular System:* Arrhythmias including PVCs and PACs (2%), angina/chest pain (1%), and hypotension (0.7%). Others including cardiac failure, asystole, bradycardia, tachycardia, and vasovagal reaction were reported with an individual incidence of 0.3% or less.

Thrombo-embolic complications have been reported in connection with contrast- enhanced angiography of coronary, cerebral, renal and peripheral arteries. The contrast agent may have contributed to the complications.
Cardiac complications including acute myocardial infarction have been reported during or after contrast-enhanced coronary angiography. Elderly patients or patients with severe coronary artery disease, unstable angina pectoris and left ventricular dysfunction had a higher risk.

In very rare occasions the contrast medium may cross the blood-brain barrier resulting in uptake of contrast medium in the cerebral cortex that may cause neurological reactions. They may include convulsions, transient motor or sensory disturbances, transient confusion, transient memory loss, and encephalopathy.

Overdosage
Overdosage may occur. The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular systems. The symptoms included: cyanosis, bradycardia, acidosis, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatment of an overdosage is directed toward the support of all vital functions, and prompt institution of symptomatic therapy.

In cases of overdose, any resulting water- or electrolyte imbalance must be corrected. Renal function should be monitored for the next 3 days. If needed, haemodialysis may be used for clearance of excessive contrast medium. There is no specific antidote.

Dosage and Administration -General
As with all radiopaque contrast agents, the lowest dose of Iohexol Injection USP 350mg I/mL necessary to obtain adequate visualization should be used. A lower dose may reduce the possibility of an adverse reaction. Most procedures do not require use of either the maximum volume or the highest concentration of Iohexol Injection USP 350mg I/mL. The combination of volume and concentration of Iohexol Injection USP 350mg I/mL to be used should be carefully individualized accounting for factors such as age, body weight, size of the vessel and the rate of blood flow within the vessel. Other factors such as anticipated pathology, degree and extent of opacification required, structure(s) or area to be examined, disease processes affecting the patient, and equipment and technique to be employed should be considered.

Sterile technique must be used in all vascular injections involving contrast media.

If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing agents.

It may be desirable that solutions of radiopaque diagnostic agents be used at body temperature when injected.

Iohexol Injection USP 350mg I/mL should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Solutions of Iohexol Injection USP 350mg I/mL should be used only if clear and within the normal colorless to pale yellow range. If particulate matter or discoloration is present, do not use.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. A separate syringe should be used.

Shelf-Life
The expiry date of the product is indicated on the packaging materials

Special Precautions for Storage
Iohexol Injection USP 350mg I/mL should be stored up to 30ºC protected from light. Vials are intended for single use any unused portions must be discarded.

Nature and content of container
Glass vials and bottles:
The product is filled in injection in glass vials (100 ml) closed with rubber stoppers and sealed with combined "flip off seal/tear off seal - flat plast disc".

The product should be drawn into the syringe immediately before use. Vials are intended for single use only; any unused portions must be discarded.

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