Each milliliter contains 100 mg of iothalamate meglumine, 0.10 mg edetate calcium disodium as a stabilizer and 0.125 mg of monobasic sodium phosphate as a buffer. The solution contains approximately 0.04 mg sodium in each milliliter (12 mg/100 mL) and provides 14.1% (1.4 g/mL) osmotically bound water (12.1 mg/mL of water). Conray 30 has a concentration of approximately 100 mOsmol per liter, an osmolality of approximately 620 mOsmol per kilogram of water, and is therefore, hypertonic under conditions of normal hydration.

The typical rate of administration is approximately 2.4 mL/min. Conray 30 is generally administered as a bolus injection.

Following intravenous administration, Conray 30 is rapidly transported through the circulatory system to the kidney and is excreted unchanged in the urine by glomerular filtration. The pharmacokinetics of intravenously administered radiopaque contrast media are usually best described by a two-compartment model with a rapid alpha phase in which the drug product is not administered and a slower beta phase in which the drug product is administered. The alpha phase is approximately 0.5 to 2 minutes, and the beta phase is approximately 2 to 8 minutes.

In patients with normal renal function, the drug is eliminated primarily through the kidneys. The drug does not occur at normal room temperatures. It is supplied in containers from which the air has been displaced by nitrogen. The drug contains no preservatives.

The iodine content of Conray 30 is 1-deoxy-1-(methylamino)-D-glucitol 5-acetamido-2,4,6-tri-O-methylphosphatathenate (salts), and has the following structural formula:

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\text{IO}_{30}^+ \quad \text{mol wt} = 415.34
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Symptoms related to the respiratory system include sneezing, nasal stuffiness, coughing, sneezing, chest tightness and wheezing, which may be initial manifestations of more severe and infrequent reactions including anaphylactic shock, laryngospasm and bronchiolitis or with or without edema, pulmonary edema, apnea and cyanosis. Rarely, these allergic-type reactions can progress into anaphylaxis with loss of consciousness and coma and severe cardiovascular disturbances.

Cardiovascular reactions: Generalized vasodilation, flushing and venous engorgement. Occasionally, tachycardia or tachydysrhythmia, fetal blood cell clumping and agglutination, cyanosis and interference in coagulation. Extremely rare cases of disseminated intravascular coagulation resulting in death have been reported. Severe cardiovascular reactions include rare cases of hypotensive shock, coronary insufficiency, cardiac arrhythmias, fibrillation and arrest. These severe reactions are usually reversible with prompt and appropriate management; however, fatalities have occurred.

Technique reactions: Extravasation with burning pain, hematomas, ecchymosis and tissue necrosis, parenthesis or numbness, vascular constriction due to injection rate, thrombosis and thrombophlebitis.

Neurologic reactions: Spasm, convulsions, aphasia, syncope, coma and death.

Other reactions: Headache, trembling, shaking, chills without fever and light-headedness. Temporary renal shutdown or other nephropathy.

OVERDOSAGE

Overdosage may occur. The adverse effects of overdosage are life-threatening and affect not only the pulmonary and cardiovascular system. The symptoms may include cyanosis, bradyarrhythmia, acidosis, pulmonary hemorrhage, convulsions, coma and cardiac arrest. Treatment of an overdose is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

Iothalamates are dialyzable.

The intravenous LD₅₀ value of various concentrations of iohexolame Meglumine (in grams of iodine/kilogram body weight) varied from 3.7 to 8.9 g/kg in mice and 9.8 to 11.2 g/kg in rats. The LD₅₀ value decreases as the rate of injection increases.

DOSAGE AND ADMINISTRATION

It is advisable that Conray 30 be at or close to body temperature when injected.

The patient should be instructed to omit the meal that precedes the examination. Appropriate premedication, which may include a barbiturate, tranquilizer or analgesic drug, may be administered prior to the examination.

A preliminary film is recommended to check the position of the patient and the x-ray exposure factor.

If during administration a minor reaction occurs the injection should be slowed or stopped until the reaction has subsided. If a major reaction occurs the injection should be discontinued immediately.

Under no circumstances should either corticosteroids or antihistamines be mixed in the same syringe with the contrast medium because of a potential for chemical incompatibility.

Parenteral drug products should be inspected visually for particulate matter and chemical incompatibility.

INTRAVENTRICAL INFUSION UROGRAPHY

Intravenous infusion urography enhances the potential for more diagnostic information in those patients in whom the usual excretory urographic technique either has not proved or is not expected to provide satisfactory visualization. The entire urinary tract, including nephrogram and cystogram, may be visualized in the unobstructed patient with normal renal function.

Patient Preparation

Appropriate preparation of the patient is important for optimal visualization. A low residue diet is recommended for the day preceding the examination and a catheter is given the evening before the examination, unless contraindicated.

Dehydration is not indicated for the performance of infusion urography. Patients should be maintained in an optimal state of hydration prior to the procedure.

Usual Dosage

The recommended adult dose is 200 to 300 mL of Conray 30 (4 mL/kg) with a maximum of 300 mL. Safety and effectiveness for infusion urography in children below the age of 12 have not been established.

The solution is infused through an appropriate IV. needle at a rate of approximately 50 mL per minute. Any appropriate intravenous administration set may be used observing the usual precautions for maintaining sterility and safety in administration. Films are usually taken at 5-10 minute intervals following the injection of the infusates for a total of 20 minutes.

In patients with impaired renal function, diagnostic spasm is achieved only after prolonged periods. In these individuals, periodic films obtained up to 24 hours after infusion might yield useful information.

CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC (CT) BRAIN IMAGING

Tumors

Conray 30 may be useful to enhance the demonstration of the presence and extent of certain malformations such as: gliomas including malignant gliomas, glioblastomas, astrocytomas, ependymomas, gangliogliomas and gangliomas, ependymomas; medulloblastomas; meningiomas; neoplasms; pial anomalies; craniopharyngiomas; germ cellomas, and metastatic lesions.

The usefulness of contrast enhancement for the investigation of the intraventricular space and low grade or infiltrative glomas has not been demonstrated.

In cases where lesions have calcified, there is less likelihood of enhancement.

Following therapy, tumors may show decreased or no enhancement.

Non-Neoplastic Conditions

The use of Conray 30 may be beneficial in the image enhancement of non-neoplastic lesions.

Cerebral infarctions of recent onset may be better visualized with the contrast enhancement; while some infarctions are obscured if contrast media are used. The use of iodinated contrast media results in contrast enhancement in about 60% of cerebral infarctions studied from one to four weeks from the onset of symptoms.

Sites of active infection may also be enhanced following contrast medium administration.

Arteriovenous malformations and aneurysms will show contrast enhancement. In the case of these vascular lesions, the enhancement is probably dependent on the iodine content of the circulating blood pool.

The opacification of the inferior vermis following contrast medium administration has resulted in false positive diagnoses in a number of normal studies.

Patient Preparation

No special patient preparation is required for contrast enhancement of CT brain scanning. However, it is advisable to ensure that patients are well hydrated prior to examination.

Usual Dosage

The recommended adult dose is 200 to 300 mL of Conray 30. For children under 12 years of age and patients weighing less than 100 pounds, a dose of 4-mL/kg (2 mL/lb) is recommended. The dose should be infused as rapidly as possible through any well-ventilated intravenous administration set and needle, observing the usual precautions for maintaining sterility.

ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY

Arterial digital subtraction angiography provides images similar in quality to conventional film-screen systems. The advantage of arterial DSA when compared to standard film angiography include the use of less contrast medium; the use of a lower concentration of contrast medium as provided by Conray 30; a decreased need for selective arterial catheterization and a shortened examination time. The limitations of arterial DSA include: reduced spatial resolution and limited field size.

Patient Preparation

No special patient preparation is required for arterial DSA. However, it is advisable to ensure that patients are well hydrated prior to examination.

Precautions

In addition to the general precautions described, the risks associated with arterial DSA are those usually attendant with catheter procedures. Following the procedure, gentle pressure hemostasis is required, followed by observation and immobilization of the limb for several hours to prevent hematomas from the site of arterial puncture.

Usual Dosage

It is advisable to inject at rates approximately equal to the flow rate of the vessel being injected. The following volumes, per injection, have been used, and may be repeated as necessary.

- Carotid in Internal Arteries: 6-10 mL
- Subclavian and Brachial Arteries: 3-5 mL
- Major branches of the Aorta: 5-10 mL
- Abdominal Aorta: 10-30 mL

HOW SUPPLIED

Conray 30 is available in 150 mL bottles in packages of 12 (NDC 2019-1552-11).

Storage: Store below 30°C (86°F). Exposing this product to very cold temperatures may result in crystallization of the salt. If this occurs the container should be brought to room temperature. Intermittent shaking may be necessary to completely redissolve the crystals. Before use, examine the product to assure that all solids are redissolved and that the container and closure have not been damaged.

This preparation is sensitive to light and must be protected from strong daylight or direct exposure to the sun.

As with all contrast media, the container should be inspected prior to use to ensure that breakage or other damage has not occurred during shipping and handling. All containers should be inspected for closure integrity. Damaged containers should not be used.

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Made in USA

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