Intravenous Procedures

Conray 43 is a sterile aqueous solution intended for use as a diagnostic radiopaque medium. Conray 43 contains 43% w/v iothalamate meglumine which is 1-deoxy-D-glucitol monoiodo-D-glucitol bisiodo-D-glucitol bisiodo-D-glucitol triiodo-D-glucitol tetraiodo-D-glucitol pentaiodo-D-glucitol hexaiodo-D-glucitol and hepta iodo-D-glucitol. Conray 43 is a clear solution containing no undissolved solids. Crystalization does not occur because of the high osmolality. It is supplied in containers from which it has been sterilized by dry heat.

Clinical Pharmacology

Conray 43 is a sterile aqueous solution intended for use as a diagnostic radiopaque medium. It is a clear solution containing no undissolved solids. Crystalization does not occur because of the high osmolality. It is supplied in containers from which it has been sterilized by dry heat.

Subcutaneous Procedures

Conray 43 is a sterile aqueous solution intended for use as a diagnostic radiopaque medium. It is a clear solution containing no undissolved solids. Crystalization does not occur because of the high osmolality. It is supplied in containers from which it has been sterilized by dry heat.

Conray 43 is a sterile aqueous solution intended for use as a diagnostic radiopaque medium. It is a clear solution containing no undissolved solids. Crystalization does not occur because of the high osmolality. It is supplied in containers from which it has been sterilized by dry heat.
The tissue necrosis due to extravasation with burning pain, hematomas, ecchymosis and/or inflammation in those patients in whom the usual excretory urographic technique was used. The use of iodinated contrast medium results in contrast enhancement in about 40% of vascular stenoses studied from one to four weeks from the onset of symptoms. Sites of active infection may also be enhanced following contrast medium administration.

Allergic reactions are rare. In the event of an allergic reaction, the patient should be kept in a hospital with regular monitoring. If necessary, additional therapy may be required.

Prophylaxis
Preparation
Preparation: There are several allergy-reducing steps that patients can take. While some patients may have only mild reactions, others may develop severe symptoms.

Adverse reactions to contrast media may be nonspecific or may be caused by a variety of factors. These reactions can range from mild to severe, and can occur within minutes to hours after the injection.

In patients with impaired renal function, diagnostic opacification frequently has resulted in failure of contrast enhancement.

Overdosage Overdosage may occur. The adverse effects of overdosage are life-threatening and may include the following: hypotensive shock, coronary artery occlusion, pulmonary edema, and death. If during administration a minor reaction occurs, the injection should be slowed. If a severe reaction occurs, the injection should be discontinued immediately. Treatment is urgent and mandatory.

CONTRAST ENHANCEMENT IN BODY COMPUTED TOMOGRAPHY Tumors

In patients with impaired renal function, diagnostic opacification frequently has resulted in failure of contrast enhancement.

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

Usual Dosage
The usual dose in adults and children is 2 mL/kg (1.5 mL/kg) by intravenous administration using a combination of both.

Pregnancy

Tumors

Conray 43 may be used to enhance the demonstration of the extent and severity of certain malignancies such as: gliomas including malignant gliomas, glioblastomas, astrocytomas, oligodendrogliomas and ependymomas; medulloblastomas; meningiomas; neoplasms; intranodular carcinomas; hepatic metastases; and mesotheliomas.

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

Tumors

The solution in infusion bags is intended for intravenous use at a rate of approximately 40 to 50 mL per minute. Any appropriate intravenous administration set may be used for obtaining the usual precautions for maintaining urinary catheterization and urinary drainage. Patients should be observed for 5 to 10 minutes following the initiation of the infusion for a total of 20 minutes.

In patients with impaired renal function, diagnostic opacification frequently has resulted in failure of contrast enhancement.
Conray™

[iothalamate meglumine injection USP 60%]

CT Scanning of the Head

Each milliliter contains 600 mg of iothalamate meglumine, 0.09 mg edetate calcium with caution, and only when the need for the examination dictates, since excretion in some cases can be prolonged.

Whenever contrast agents are administered, patients should be instructed to inform the physician if they have previously experienced a reaction to a contrast medium, if they are known to suffer from asthma or other respiratory diseases, if they are known to have sensitivity to iodinated compounds, if they have a history of bronchial asthma or allergy, including food, a family history of allergy, or a known sensitivity to the iodinated compound iothalamate meglumine. Any history of urticaria, angioneurotic edema, or other cutaneous phenomenon, or a positive test to any medical examination for contrast media is contraindicated.

Indications and Usage

CT Scanning of the Head

1. For CT scanning of the head, Conray™ is a non-ionic, high osmolality iodinated contrast medium for intravenous injection. It is used to delineate the brain and its contents and to enhance soft tissue and bone structures.

2. It is used in the differentiation of normal and abnormal intracranial structures, and in the detection of abnormalities such as tumors, abscesses, aneurysms, arteriovenous malformations, hemorrhage, and inflammation.

3. It is also used in the evaluation of the sella turcica, pituitary gland, optic nerves, and other structures within the skull.

4. Conray™ is indicated for the enhancement of CT images of the head, providing clearer delineation of the brain and its contents.

Contraindications

CT Scanning of the Head

1. Conray™ is contraindicated in patients with a known sensitivity to iothalamate meglumine or other iodinated contrast agents.

2. It is contraindicated in patients with a history of severe adverse reactions to contrast media, such as anaphylaxis or anaphylactic shock.

3. Conray™ should not be used in patients with a history of severe reactions to any iodinated contrast agent.

4. It is also contraindicated in patients with a history of severe reactions to other non-ionic contrast media.

5. Conray™ is contraindicated in patients with a history of severe reactions to intravenous injection of any other iodinated contrast agent.

6. It is contraindicated in patients with a history of severe reactions to intravenous injection of any other non-ionic contrast agent.

Precautions

CT Scanning of the Head

1. Patients should be carefully examined before the injection of Conray™.

2. The use of Conray™ in patients with a history of atopy or other allergies should be approached with caution.

3. Conray™ should be used with caution in patients with a history of renal insufficiency or renal failure.

4. Conray™ should be used with caution in patients with a history of hepatic disease.

5. Conray™ should be used with caution in patients with a history of cardiac disease.

6. Conray™ should be used with caution in patients with a history of pulmonary disease.

7. Conray™ should be used with caution in patients with a history of gastrointestinal disease.

8. Conray™ should be used with caution in patients with a history of endocrine disease.

9. Conray™ should be used with caution in patients with a history of hematological disease.

10. Conray™ should be used with caution in patients with a history of infectious disease.

11. Conray™ should be used with caution in patients with a history of oncological disease.

12. Conray™ should be used with caution in patients with a history of dermatological disease.

13. Conray™ should be used with caution in patients with a history of musculoskeletal disease.

14. Conray™ should be used with caution in patients with a history of neurological disease.

15. Conray™ should be used with caution in patients with a history of psychiatric disease.

16. Conray™ should be used with caution in patients with a history of ophthalmological disease.

17. Conray™ should be used with caution in patients with a history of otological disease.

18. Conray™ should be used with caution in patients with a history of rhinological disease.

19. Conray™ should be used with caution in patients with a history of dental disease.

20. Conray™ should be used with caution in patients with a history of orthopedic disease.

21. Conray™ should be used with caution in patients with a history of urological disease.

22. Conray™ should be used with caution in patients with a history of gynecological disease.

23. Conray™ should be used with caution in patients with a history of neurological disease.

24. Conray™ should be used with caution in patients with a history of ophthalmological disease.

25. Conray™ should be used with caution in patients with a history of otological disease.

26. Conray™ should be used with caution in patients with a history of rhinological disease.

27. Conray™ should be used with caution in patients with a history of dental disease.

28. Conray™ should be used with caution in patients with a history of orthopedic disease.

29. Conray™ should be used with caution in patients with a history of urological disease.

30. Conray™ should be used with caution in patients with a history of gynecological disease.

31. Conray™ should be used with caution in patients with a history of neurological disease.

32. Conray™ should be used with caution in patients with a history of ophthalmological disease.

33. Conray™ should be used with caution in patients with a history of otological disease.

34. Conray™ should be used with caution in patients with a history of rhinological disease.

35. Conray™ should be used with caution in patients with a history of dental disease.

36. Conray™ should be used with caution in patients with a history of orthopedic disease.

37. Conray™ should be used with caution in patients with a history of urological disease.

38. Conray™ should be used with caution in patients with a history of gynecological disease.

39. Conray™ should be used with caution in patients with a history of neurological disease.

40. Conray™ should be used with caution in patients with a history of ophthalmological disease.

41. Conray™ should be used with caution in patients with a history of otological disease.

42. Conray™ should be used with caution in patients with a history of rhinological disease.

43. Conray™ should be used with caution in patients with a history of dental disease.

44. Conray™ should be used with caution in patients with a history of orthopedic disease.

45. Conray™ should be used with caution in patients with a history of urological disease.

46. Conray™ should be used with caution in patients with a history of gynecological disease.

47. Conray™ should be used with caution in patients with a history of neurological disease.

48. Conray™ should be used with caution in patients with a history of ophthalmological disease.

49. Conray™ should be used with caution in patients with a history of otological disease.

50. Conray™ should be used with caution in patients with a history of rhinological disease.

51. Conray™ should be used with caution in patients with a history of dental disease.

52. Conray™ should be used with caution in patients with a history of orthopedic disease.

53. Conray™ should be used with caution in patients with a history of urological disease.

54. Conray™ should be used with caution in patients with a history of gynecological disease.

55. Conray™ should be used with caution in patients with a history of neurological disease.

56. Conray™ should be used with caution in patients with a history of ophthalmological disease.

57. Conray™ should be used with caution in patients with a history of otological disease.

58. Conray™ should be used with caution in patients with a history of rhinological disease.

59. Conray™ should be used with caution in patients with a history of dental disease.

60. Conray™ should be used with caution in patients with a history of orthopedic disease.

61. Conray™ should be used with caution in patients with a history of urological disease.

62. Conray™ should be used with caution in patients with a history of gynecological disease.

63. Conray™ should be used with caution in patients with a history of neurological disease.

64. Conray™ should be used with caution in patients with a history of ophthalmological disease.

65. Conray™ should be used with caution in patients with a history of otological disease.

66. Conray™ should be used with caution in patients with a history of rhinological disease.

67. Conray™ should be used with caution in patients with a history of dental disease.

68. Conray™ should be used with caution in patients with a history of orthopedic disease.

69. Conray™ should be used with caution in patients with a history of urological disease.

70. Conray™ should be used with caution in patients with a history of gynecological disease.

71. Conray™ should be used with caution in patients with a history of neurological disease.

72. Conray™ should be used with caution in patients with a history of ophthalmological disease.

73. Conray™ should be used with caution in patients with a history of otological disease.

74. Conray™ should be used with caution in patients with a history of rhinological disease.

75. Conray™ should be used with caution in patients with a history of dental disease.

76. Conray™ should be used with caution in patients with a history of orthopedic disease.

77. Conray™ should be used with caution in patients with a history of urological disease.

78. Conray™ should be used with caution in patients with a history of gynecological disease.

79. Conray™ should be used with caution in patients with a history of neurological disease.

80. Conray™ should be used with caution in patients with a history of ophthalmological disease.

81. Conray™ should be used with caution in patients with a history of otological disease.

82. Conray™ should be used with caution in patients with a history of rhinological disease.

83. Conray™ should be used with caution in patients with a history of dental disease.

84. Conray™ should be used with caution in patients with a history of orthopedic disease.

85. Conray™ should be used with caution in patients with a history of urological disease.

86. Conray™ should be used with caution in patients with a history of gynecological disease.

87. Conray™ should be used with caution in patients with a history of neurological disease.

88. Conray™ should be used with caution in patients with a history of ophthalmological disease.

89. Conray™ should be used with caution in patients with a history of otological disease.

90. Conray™ should be used with caution in patients with a history of rhinological disease.

91. Conray™ should be used with caution in patients with a history of dental disease.

92. Conray™ should be used with caution in patients with a history of orthopedic disease.

93. Conray™ should be used with caution in patients with a history of urological disease.

94. Conray™ should be used with caution in patients with a history of gynecological disease.

95. Conray™ should be used with caution in patients with a history of neurological disease.

96. Conray™ should be used with caution in patients with a history of ophthalmological disease.

97. Conray™ should be used with caution in patients with a history of otological disease.

98. Conray™ should be used with caution in patients with a history of rhinological disease.

99. Conray™ should be used with caution in patients with a history of dental disease.

100. Conray™ should be used with caution in patients with a history of orthopedic disease.
sufficient to visualize the entire ductal system. If desired, the contrast agent may be injected slowly, using a large-bore needle, over a 15-30 second period. The dye should be used with an infusion pump or similar device to help plan surgery. The technique may also be of value in avoiding laparotomy in the evaluation of upper abdominal masses, as well as in the investigation of splenic abnormalities.

**Precautions**

In addition to the general precautions previously described, the patient should be placed on a cardiac monitor immediately upon entry into the examination area and continuously monitored for the duration of the examination. The patient should be observed for signs of hypotension and cardiac arrhythmias. The patient should be adequately hydrated prior to the procedure.

**DIRECTIONS FOR ADMINISTRATION**

The solution of contrast medium is administered intravenously. The usual volume of contrast medium ranges from 10 to 50 mL. The dose is determined by the size and condition of the ductal system to be opacified. The injection rate is controlled by the infusion pump. The rate of injection should be adjusted to provide optimal opacification of the ductal system. The injection should be completed over a period of 5-10 seconds. The procedure is usually performed following percutaneous transhepatic cholangiography.

**Usual Dosage**

The usual dose of contrast medium is 10-50 mL, depending on the size and condition of the ductal system to be opacified. The injection rate is controlled by the infusion pump. The rate of injection should be adjusted to provide optimal opacification of the ductal system. The injection should be completed over a period of 5-10 seconds. The procedure is usually performed following percutaneous transhepatic cholangiography.

**Adverse Reactions**

Adverse reactions that have occurred which are attributable to either the procedure or the contrast medium include: hypotension, bradycardia, respiratory distress, and chest pain. In addition, there have been reports of joint pain or discomfort which is usually mild and transient but occasionally may be severe. There have also been reports of allergic reactions, including anaphylaxis, which may occur in patients with a history of atopy.

**REFERENCES**

Injection USP 30%)

about ten minutes; thereafter the fall becomes exponential. Maximum contrast
next five to ten minutes. This can be accounted for by the dilution in the vascular
the degree of enhancement is directly related to the amount of iodine
through the gallbladder and into the small intestine sharply increases.
the main route of excretion seems to be related to the affinity of the contrast
permit visualization until significant hemodilution occurs.

The delay in maximum contrast enhancement can range from five to forty
months, depending on the peak iodine levels achieved and the cell type of

Prophylactic therapy including corticosteroids and antimetabolites should be
available. If a serious reaction should occur, immediately discontinue

Serious or fatal reactions have been associated with the administration of
eliminate the likelihood of in vitro clotting. For these reasons, meticulous
administration technique is necessary, particularly during angiographic
and stroke have been reported during angiographic procedures with both

Serious adverse reactions have been reported due to

Successful administration of Conray 30 has been reported in many patients with
endotoxemia and/or those with elevated body temperatures. Preparatory
dephallogry is mandatory and may contribute to acute renal failure in infants, young children, the elderly, patients with pre-existing renal disease, and patients with advanced vascular disease.

Contrast agents should be carried out under the direction of personnel
adequate and well controlled studies in pregnant women. Because

Serious reactions include all other reactions. They occur more

idiosyncratic reaction in patients who have previously received a contrast

The drug contains approximately 0.04 mg sodium, 0.015 mg calcium disodium as a stabilizer and 0.125 mg of monobasic sodium phosphate

Inadvertent intrathecal injection of Conray 30 is indicated for use in intravenous infusion urography, contrast

6. Inform your physician if you are diabetic or if you have multiple

The incidence of reactions in nursing infants has not been studied. If a serious

In patients with advanced renal disease, iodinated radiopaque media should be used with caution, and only when the need for the examination dictates it, since extrarenal excretion of the iodine may be impaired. Patients with

renal function, the lesion is not visualized for the first 5 to 10 minutes after injection, after which time the lesion becomes more apparent, and the blood pool is seen to be

serious adverse reactions to Conray 30 include anaphylaxis, severe

Conray 30 is a sterile aqueous solution intended for use as a diagnostic radiographic medium. Conray 30 contains 30% w/v iodinated meglumine

The drug contains approximately 0.04 mg sodium in each
calcium disodium as a stabilizer and 0.125 mg of monobasic sodium phosphate

Reference ID: 3788316
Symptoms related to the respiratory system include sneezing, nasal stuffiness, coughing, chocking, chest tightness and wheezing, which may be initial manifestations of more severe and infrequent reactions including asthmatic attack, laryngospasm and bronchospasm 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 tachyarrhythmia. Red blood cell clumping and agglutination, cyanosis and interference in clot formation. Extreme rare cases of disseminated intravascular coagulation resulting in death have been reported. Severe cardiovascular responses include rare cases of hypotension, shock, coronary insufficiency, cardiac arrhythmia, fibrillation and arrest. These severe reactions are usually reversible with prompt and appropriate management; however, fatalities have occurred.

Endocrine reactions: Thyroid function tests indicative of hyperthyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for hypothyroidism. Technique reactions: Extravasation with burning pain, hematoma, ecchymosis and tissue necrosis, pancreatitis or numbness, vascular constiction due to injection rate, thrombosis and thrombophlebitis.

Neurological reactions: Seizures, convulsions, aspasia, syncope, coma and death.

Other reactions: Headache, trembling, chills, without fever and rigors and headache. Temporary renal dysfunction or other nephropathy.

OVERRIDING
Oversedose may occur. The adverse effects of overdose are life-threatening and affect mainly the pulmonary and cardiovascular system. The symptoms may include cyanosis, bradycardia, scissures, pulmonary hemorrhage, convulsions, coma and cardiac arrest. Treatment of an overdose is directed toward the support of all vital functions and prompt elimination of symptomatic therapy.

Iothalamate salts are dialyzable. The intravenous LD₅₀ value of various concentrations of Iothalamate Meglumine (in grams of iodine/kilogram body weight) varied from 5.7 to 8.9 g/kg in mice and 9.6 to 11.2 g/kg in rats. The LD₅₀ values decrease as the rate of injection increases.

DOSE 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 procedure, gentle pressure hemostasis is required, followed by

Vessel being injected. The following volumes, per injection, have been used, maintaining sterility and safety in administration. Films are usually taken at 5-minute intervals following the injection of the solution for a total of 20 minutes.

In patients with impaired renal function, diagnostic opacification frequently obtained up to 24 hours after infusion might yield useful information.

CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC (CT) BRACHYANG

Technique reactions:

Non-neoplastic conditions:

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 specificity of the inferior vena cava 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. Moreover, 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-sealed 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 advantages 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 temporal frame 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 hematoma 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 or Vertebral Arteries: 5–10 mL
- Aortic Arch: 15–30 mL
- Subclavian and Brachial Arteries: 5–15 mL
- Major Branches of the Aorta: 5–30 mL
- Abdominal Aorta: 10–30 mL

A total dose of 250 mL (representing 31.2 grams of iodine) should not be exceeded. Consideration should be given to the patient’s clinical condition and whether large volumes of fluids may be detrimental to patient care.

HOW SUPPLIED

Conray 30 is available in 150 mL bottles in packages of 12 (NDC 0109-8952-11). 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.

Mallock, the "M" brand mark, the MallockPharmaceuticals logo and other brands are trademarks of a Mallock-Bohdan company.

© 2015 Mallinckrodt.

Manufactured by: Liebel-Flarsheim Company LLC
Raleigh, NC 27616

Made in USA

MBO 0910 2015

Revised 02/15