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PENTETATE CALCIUM TRISODIUM

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POISINDEX® Managements

PENTETATE CALCIUM TRISODIUM

0.0 OVERVIEW

LIFE SUPPORT

CLINICAL EFFECTS

LABORATORY/MONITORING

TREATMENT OVERVIEW

RANGE OF TOXICITY

0.1 LIFE SUPPORT

A) This overview assumes that basic life support measures have been instituted.

0.2 CLINICAL EFFECTS

0.2.1 SUMMARY OF EXPOSURE

A) WITH THERAPEUTIC USE

1) Chest pain, fever, chills, headache, lightheadedness, dermatitis, pruritus, nausea, vomiting, metallic taste, diarrhea, and Injection site reactions have been reported following therapeutic use of **pentetate** zinc trisodium (Ca-DTPA). In addition, Ca-DTPA therapy has been associated with trace element deficiency including zinc, magnesium, and manganese depletion. Cough and/or wheezing have been reported in 2 patients who received nebulized Ca-DTPA; one patient had a history of asthma.

B) WITH POISONING/EXPOSURE

1) Deaths have been reported in patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection.

0.2.3 VITAL SIGNS

A) WITH THERAPEUTIC USE

1) Fever and chills have been reported with Ca-DTPA treatment (Anon, 2002).

0.2.20 REPRODUCTIVE

A) **Pentetate** calcium trisodium (Ca-DTPA) is believed to be teratogenic based on multiple-dose studies in animals. In humans, multiple doses of Ca-DTPA increase the risk of adverse reproductive outcomes. It is recommended that chelation treatment for pregnant women begin and continue with **pentetate** zinc trisodium (Zn-DTPA). In cases of high internal contamination with radioactive material, the risk of radiation-induced toxicity to the mother and fetus must be weighed against the risk of toxicity with Ca-DTPA therapy.

B) The US Food and Drug Administration's Pregnancy Category C.

0.3 LABORATORY/MONITORING

A) Monitor fluid and electrolyte status in patients with significant vomiting and/or diarrhea.

B) Monitor serum electrolytes and essential metals and obtain complete blood counts.

0.4 TREATMENT OVERVIEW

0.4.3 INHALATION EXPOSURE

A) There is limited information on **pentetate** calcium trisodium overdose. In cases of **pentetate** calcium trisodium overdose, treatment should be symptomatic and supportive.

B) INHALATION: Move patient to fresh air. Monitor for respiratory distress. If cough or difficulty breathing develops, evaluate for respiratory tract irritation, bronchitis, or pneumonitis. Administer oxygen and assist ventilation as required. Treat bronchospasm with inhaled beta2 agonist and oral or parenteral corticosteroids.

0.4.6 PARENTERAL EXPOSURE

A) There is limited information on **pentetate** calcium trisodium overdose. In cases of **pentetate** calcium trisodium overdose, treatment should be symptomatic and supportive.
B) ALLERGIC REACTION: MILD/MODERATE: antihistamines with or without inhaled beta agonists, corticosteroids or epinephrine. SEVERE: oxygen, aggressive airway management, antihistamines, epinephrine (ADULT: 0.3 to 0.5 mL of a 1:1000 solution subcutaneously; CHILD: 0.01 mL/kg, 0.5 ml max; may repeat in 20 to 30 min), corticosteroids, ECG monitoring, and IV fluids.

0.5 RANGE OF TOXICITY

A) **Pentetate** calcium trisodium (Ca-DTPA) is usually well-tolerated. Deaths have been reported in three patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection. After receiving 14 grams of Ca-DTPA, one patient became comatose and died. The other two patients died after 14 days of daily treatment. Another patient with a less severe case of hemochromatosis did not experience any adverse effects after receiving 30 grams of Ca-DTPA by intravenous injection over 12 days.

1.0 SUBSTANCES INCLUDED/SYNONYMS

THERAPEUTIC/TOXIC CLASS

SPECIFIC SUBSTANCES

AVAILABLE FORMS/SOURCES

1.1 THERAPEUTIC/TOXIC CLASS

A) **Pentetate** calcium trisodium (Ca-DTPA), a chelating agent, increases the rates of radiocontaminant elimination by forming stable chelates with metal ions.

1.2 SPECIFIC SUBSTANCES

1) Ca-DTPA
2) Calcium trisodium DTPA
3) Calcium trisodium nitrilodiethylenedintrilopenta-acetate
4) NSC-34249
5) **Pentetate** calcium trisodium
6) Pentetato calcico trisodico
7) Trisodium calcium diethylenetriaminepentaacetate
8) Molecular formula: C14-H18-Ca-N3-Na3-O10
9) CAS 12111-24-9

1.6 AVAILABLE FORMS/SOURCES

A) FORMS

1) Ca-DTPA is available as a sterile solution in 5 mL single-use clear glass ampoules (1000 mg of Ca-DTPA per ampoule) at a concentration of 200 mg/mL for intravenous use. Each mL has 200 mg of Ca-DTPA (obtained from 158.17 mg pentetic acid, 40.24 mg calcium carbonate and NaOH) in water for injection, USP. If internal contamination is only by inhalation within the preceding 24 hours, patients can receive Ca-DTPA by nebulized inhalation (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

B) USES

1) **Pentetate** calcium trisodium (Ca-DTPA) is used to treat individuals with known or suspected internal contamination with transuranium ions, specifically plutonium, americium, and/or curium, to increase rates of elimination (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.0 CLINICAL EFFECTS

3.1 SUMMARY OF EXPOSURE

A) WITH THERAPEUTIC USE

1) Chest pain, fever, chills, headache, lightheadedness, dermatitis, pruritus, nausea, vomiting, metallic taste, diarrhea, and Injection site reactions have been reported following therapeutic use of **pentetate** zinc trisodium (Ca-DTPA). In addition, Ca-DTPA therapy has been associated with trace element deficiency including zinc, magnesium, and manganese depletion. Cough and/or wheezing have been reported in 2 patients who received nebulized Ca-DTPA; one patient had a history of asthma.

B) WITH POISONING/EXPOSURE

1) Deaths have been reported in patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection.

3.3 VITAL SIGNS

3.3.1 SUMMARY

A) WITH THERAPEUTIC USE

1) Fever and chills have been reported with Ca-DTPA treatment (Anon, 2002).

3.5 CARDIOVASCULAR

3.5.2 CLINICAL EFFECTS

A) CHEST PAIN

1) WITH THERAPEUTIC USE

a) Chest pain has been reported with Ca-DTPA treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.6 RESPIRATORY

3.6.2 CLINICAL EFFECTS

A) RESPIRATORY FINDING

1) WITH THERAPEUTIC USE

a) Cough and/or wheezing have been reported in 2 patients who received nebulized Ca-DTPA; one patient had a history of asthma (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.7 NEUROLOGIC

3.7.2 CLINICAL EFFECTS

A) CENTRAL NERVOUS SYSTEM FINDING

1) WITH THERAPEUTIC USE

a) Headache and lightheadedness have been reported with Ca-DTPA treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

b) Anosmia was reported in a patient receiving 27 months of therapy with Ca-DTPA (over 123 grams total dose). The loss of smell was possibly related to zinc depletion. Discontinuation of Ca-DTPA resulted in an improvement in the patient's sense of smell (Anon, 2002).

3.8 GASTROINTESTINAL

3.8.2 CLINICAL EFFECTS

A) GASTROINTESTINAL TRACT FINDING

1) WITH THERAPEUTIC USE

a) Nausea, vomiting, metallic taste, and diarrhea have been reported with Ca-DTPA treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004; Anon, 2002).

3.10 GENITOURINARY

3.10.2 CLINICAL EFFECTS

A) BLOOD IN URINE

1) WITH THERAPEUTIC USE

a) Microhematuria has been reported with Ca-DTPA treatment (Brugsch et al, 1965).

3.14 DERMATOLOGIC

3.14.2 CLINICAL EFFECTS

A) DERMATITIS

1) WITH THERAPEUTIC USE

a) Dermatitis and pruritus have been reported with Ca-DTPA treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004; Anon, 2002).

3.17 METABOLISM

3.17.2 CLINICAL EFFECTS

A) METABOLIC FINDING

1) WITH THERAPEUTIC USE

a) Ca-DTPA therapy has been associated with endogenous trace element deficiency including zinc, magnesium, and manganese depletion. This depletion may be more pronounced with split daily dosing, increased doses, and with longer treatment duration (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.19 IMMUNOLOGIC

3.19.2 CLINICAL EFFECTS

A) ACUTE ALLERGIC REACTION

1) WITH THERAPEUTIC USE

a) Allergic reaction has been reported with Ca-DTPA treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.20 REPRODUCTIVE

3.20.1 SUMMARY

A) **Pentetate** calcium trisodium (Ca-DTPA) is believed to be teratogenic based on multiple-dose studies in animals. In humans, multiple doses of Ca-DTPA increase the risk of adverse reproductive outcomes. It is recommended that chelation treatment for pregnant women begin and continue with **pentetate** zinc trisodium

(Zn-DTPA). In cases of high internal contamination with radioactive material, the risk of radiation-induced toxicity to the mother and fetus must be weighed against the risk of toxicity with Ca-DTPA therapy.

B) The US Food and Drug Administration's Pregnancy Category C.

3.20.2 TERATOGENICITY

A) ANIMAL STUDIES

1) Ca-DTPA is believed to be teratogenic based on multiple-dose studies in animals and because chelation therapy results in depletion of zinc in the body, which is known to affect DNA and RNA synthesis in humans (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

2) Mouse studies have demonstrated teratogenic and embryocidal effects of multiple doses of Ca-DTPA. Mice received 5 daily injections of Ca-DTPA at doses 2 to 8 times the recommended daily human dose. A higher incidence of gross malformations (eg; exencephaly, spina bifida, and cleft palate) was observed at higher doses, with a higher susceptibility in early and mid gestation. Five daily injections at doses approximately equivalent to the recommended human dose did not produce harmful effects in mice (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3) A study of 2 pregnant dogs given daily injections of Ca-DTPA demonstrated severe teratogenic effects, especially fetal brain damage. Ca-DTPA was administered from implantation until parturition at a dose approximately 50% of the recommended human dose (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.20.3 EFFECTS IN PREGNANCY

A) PREGNANCY CATEGORY

1) The US Food and Drug Administration's Pregnancy Category C (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

2) Multiple doses of Ca-DTPA increase the risk of adverse reproductive outcomes. It is recommended that chelation treatment for pregnant women begin and continue with **pentetate** zinc trisodium (Zn-DTPA), if available, except in cases of high internal contamination with radioactive material. In these cases, the risk of radiation-induced toxicity to the mother and fetus must be weighed against the risk of toxicity with Ca-DTPA therapy. Since Ca-DTPA is more effective than Zn-DTPA in the first 24 hours after internal contamination, a single dose of Ca-DTPA with zinc-containing vitamin and mineral supplements may be appropriate initial treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.20.4 EFFECTS DURING BREAST-FEEDING

A) BREAST MILK

1) It is unknown if Ca-DTPA is excreted in breast milk. However, radiocontaminants are known to be excreted in breast milk. Whether receiving chelation therapy or not, women with suspected or known internal contamination should not breast feed. Precautions should be taken when discarding breast milk (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

3.21 CARCINOGENICITY

3.21.1 IARC CATEGORY

A) IARC Carcinogenicity Ratings for CAS12111-24-9 (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2006; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010a; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2008; IARC, 2004):

1) Not Listed

3.23 OTHER

3.23.2 CLINICAL EFFECTS

A) INJECTION SITE REACTION

1) WITH THERAPEUTIC USE

a) Injection site reactions have been reported with Ca-DTPA treatment (Prod Info **Pentetate** Trisodium Injection, 2004; Brugsch et al, 1965). Injection site reactions have been reported in 8 individuals following the intramuscular use of Ca-DTPA (Anon, 2004).

B) HEMOCHROMATOSIS

1) WITH POISONING/EXPOSURE

a) Deaths have been reported in 3 patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection. After receiving 14 grams of Ca-DTPA,

one patient became comatose and died. The other 2 patients died after 14 days of daily treatment (Prod Info **Pentetate** Calcium Trisodium Injection, 2004). Another patient with a less severe case of hemochromatosis did not experience any adverse effects after receiving 30 grams of Ca-DTPA by intravenous injection over 12 days (Anon, 2004).

4.0 LABORATORY/MONITORING

4.1 MONITORING PARAMETERS/LEVELS

4.1.1 SUMMARY

A) Monitor fluid and electrolyte status in patients with significant vomiting and/or diarrhea.

B) Monitor serum electrolytes and essential metals and obtain complete blood counts.

4.1.2 SERUM/BLOOD

A) Monitor CBC with differential, BUN, serum chemistry and electrolytes (including calcium, zinc, magnesium and manganese) and urinalysis regularly during therapy.

4.1.4 OTHER

A) OTHER

1) Measure the radioactivity in blood, urine, and fecal samples weekly to monitor the radioactive contaminant elimination rate. A baseline estimate of the total body burden of transuranium element should be obtained by whole-body counting and bioassay when possible.

6.0 TREATMENT

LIFE SUPPORT

MONITORING

ORAL EXPOSURE

PARENTERAL EXPOSURE

INHALATION EXPOSURE

ENHANCED ELIMINATION

6.1 LIFE SUPPORT

A) Support respiratory and cardiovascular function.

6.4 MONITORING

A) Monitor fluid and electrolyte status in patients with significant vomiting and/or diarrhea.

B) Monitor serum electrolytes and essential metals and obtain complete blood counts.

6.5 ORAL EXPOSURE

6.5.1 PREVENTION OF ABSORPTION/PREHOSPITAL

A) SUMMARY

1) **Pentetate** calcium trisodium is only available for intravenous or inhalation use. In the unlikely event of ingestion, administer activated charcoal.

6.5.3 TREATMENT

A) GENERAL TREATMENT

1) See the PARENTERAL EXPOSURE treatment section for further information.

6.6 PARENTERAL EXPOSURE

6.6.2 TREATMENT

A) SUPPORT

1) There is limited information on **pentetate** calcium trisodium overdose. In cases of **pentetate** trisodium overdose, treatment should be symptomatic and supportive.

B) MONITORING OF PATIENT

1) Monitor fluid and electrolyte status in patients with significant vomiting and/or diarrhea.

2) Monitor serum electrolytes and essential metals and obtain complete blood counts.

C) BRONCHOSPASM

1) BRONCHOSPASM SUMMARY

a) Administer beta2 adrenergic agonists. Consider use of inhaled ipratropium and systemic corticosteroids. Monitor peak expiratory flow rate, monitor for hypoxia and respiratory failure, and administer oxygen as necessary.

2) ALBUTEROL/ADULT DOSE

a) 2.5 to 5 milligrams diluted with 4 milliliters of 0.9% saline by nebulizer every 20 minutes for three doses. If incomplete response, administer 2.5 to 10 milligrams every 1 to 4 hours as needed OR administer 10 to 15 milligrams every hour by continuous nebulizer as needed. Consider adding ipratropium to the nebulized albuterol; DOSE: 0.5 milligrams by nebulizer every 30 minutes for three doses then every 2 to 4 hours as needed, NOT administered as a single agent (National Heart,Lung,and Blood Institute, 2007).

3) ALBUTEROL/PEDIATRIC DOSE

a) 0.15 milligram/kilogram (minimum 2.5 milligrams) diluted with 4 milliliters of 0.9% saline by nebulizer every 20 minutes for three doses. If incomplete response administer 0.15 to 0.3 milligram/kilogram (maximum 10 milligrams) every 1 to 4 hours as needed OR administer 0.5 mg/kg/hr by continuous nebulizer as needed. Consider adding ipratropium to the nebulized albuterol; DOSE: 0.25 to 0.5 milligrams by nebulizer every 20 minutes for three doses then every 2 to 4 hours as needed, NOT administered as a single agent (National Heart,Lung,and Blood Institute, 2007).

4) ALBUTEROL/CAUTIONS

a) Monitor for tachycardia, tremors.

5) CORTICOSTEROIDS

a) Consider systemic corticosteroids in patients with significant bronchospasm. PREDNISONE: ADULT: 40 to 80 milligrams/day in 1 or 2 divided doses. CHILD: 1 to 2 milligrams/kilogram/day (maximum 60 mg) in 1 or 2 divided doses (National Heart,Lung,and Blood Institute, 2007). Tapering not required for short courses. SOLUMEDROL: ADULT: 125 milligrams intravenously as initial dose, followed by 120 to 180 milligrams/day in three or four divided doses for 48 hours. CHILD: 1 milligram/kilogram intravenously, may repeat every 6 hours for 48 hours. Switch to an oral agent as soon as practical.

D) IMMUNE HYPERSENSITIVITY REACTION

1) SUMMARY

a) Mild to moderate allergic reactions may be treated with antihistamines with or without inhaled beta adrenergic agonists, corticosteroids or epinephrine. Treatment of severe anaphylaxis also includes oxygen supplementation, aggressive airway management, epinephrine, ECG monitoring, and IV fluids.

2) BRONCHOSPASM

a) ALBUTEROL

1) ADULTS: 2.5 to 5 milligrams in 2 to 4.5 milliliters of normal saline delivered per nebulizer every 20 minutes up to 3 doses. If incomplete response administer 2.5 to 10 mg every 1 to 4 hours as needed, or 10 to 15 mg/hr by continuous nebulization as needed (National Heart,Lung,and Blood Institute, 2007). CHILDREN: 0.15 milligram/kilogram (minimum 2.5 milligrams) per nebulizer every 20 minutes up to 3 doses. If incomplete response administer 0.15 to 0.3 mg/kg (up to 10 mg) every 1 to 4 hours as needed, or 0.5 mg/kg/hr by continuous nebulization (National Heart,Lung,and Blood Institute, 2007).

3) CORTICOSTEROIDS

a) METHYLPREDNISOLONE - Adults: 1 to 2 milligrams/kilogram intravenously every 6 to 8 hours. Children: 1 to 2 milligrams/kilogram intravenously (maximum 125 milligrams) every 6 hours.

b) PREDNISONE - Adults: 40 to 60 milligrams/day. Children: 1 to 2 milligrams/kilogram/day divided twice daily. Prolonged therapy generally not needed.

4) MILD CASES

a) DIPHENHYDRAMINE

1) ADULTS: 50 milligrams orally, intravenously, or intramuscularly initially, then 25 to 50

milligrams orally every 4 to 6 hours for 24 to 72 hours.

2) CHILDREN: 1.25 milligrams/kilogram orally, intravenously, or intramuscularly initially, then 5 milligrams/kilogram/day orally in four divided doses for 24 to 72 hours.

5) MODERATE CASES

a) EPINEPHRINE: 0.3 to 0.5 milliliter of a 1:1000 solution subcutaneously or intramuscularly (children: 0.01 milliliter/kilogram, 0.5 milliliter maximum); may repeat in 20 to 30 minutes (American Heart Association, 2005).

6) SEVERE CASES

a) EPINEPHRINE

1) INTRAVENOUS BOLUS: 1:10,000 solution, 5 to 10 milliliters diluted in 10 milliliters 0.9% saline slow intravenous push over 5 to 10 minutes (American Heart Association, 2005) (children: 0.1 milliliter/kilogram); give if systolic blood pressure less than 70 mmHg (adults); it is safest to titrate to effect in small increments, 1 to 2 milliliters at a time.

2) INTRAVENOUS INFUSION: An alternative method of intravenous epinephrine by constant infusion has been advocated as safer: 1 milligram of a 1:1000 dilution of epinephrine added to 250 milliliters dextrose 5 percent in water. Start infusion at 1 microgram/minute and titrate to systolic blood pressure of 100 mmHg (or mean arterial pressure of 80 mmHg).

7) AIRWAY MANAGEMENT

a) OXYGEN: 5 to 10 liters/minute via high flow mask.

b) INTUBATION: Perform early if any stridor or signs of airway obstruction.

c) CRICOTHYROTOMY: Use if unable to intubate with complete airway obstruction.

d) BRONCHODILATORS are recommended for mild to severe bronchospasm.

e) ALBUTEROL: ADULTS: 5 to 10 milligrams in 2 to 4.5 milliliters of normal saline delivered per nebulizer every 20 minutes up to 3 doses. If incomplete response repeat every hour. CHILDREN: 0.15 milligram/kilogram (minimum 2.5 milligrams) per nebulizer every 20 minutes up to 3 doses. If incomplete response repeat every hour.

8) MONITORING

a) CARDIAC MONITOR: All complicated cases.

b) IV ACCESS: Routine in all complicated cases.

9) HYPOTENSION

a) IF hypotensive give 500 to 2000 milliliters crystalloid initially (20 milliliters/kilogram in children) and titrate to desired effect (stabilization of vital signs, mentation, urine output); adults may require up to 6 to 10 liters/24 hours. Central venous or pulmonary artery pressure monitoring is recommended in patients with persistent hypotension.

1) VASOPRESSORS: Should be used in refractory cases unresponsive to repeated doses of epinephrine and after vigorous intravenous crystalloid rehydration.

2) DOPAMINE: Mix 400 to 800 milligrams in 250 milliliters of dextrose 5 percent in water (1600 or 3200 micrograms/milliliter). Initial dose is 2 to 5 micrograms/kilogram/minute intravenously; titrate to desired hemodynamic response.

10) DIPHENHYDRAMINE

a) ADULTS: 50 milligrams intravenously initially, then 25 to 50 milligrams intravenously or orally every 4 to 6 hours for 24 to 72 hours.

b) CHILDREN: 2 milligrams/kilogram intravenously initially, then 5 milligrams/kilogram/day intravenously or orally in four divided doses for 24 to 72 hours.

11) METHYLPREDNISOLONE

a) Adults: 1 to 2 milligrams/kilogram intravenously every 6 to 8 hours. Children: 1 to 2 milligrams/kilogram intravenously (maximum 125 milligrams) every 6 hours.

12) DYSRHYTHMIAS

a) Dysrhythmias may occur primarily or iatrogenically as a result of pharmacologic treatment (epinephrine). Monitor and correct serum electrolytes, oxygenation and tissue perfusion. Treat with antiarrhythmic agents as indicated.

E) ENHANCED ELIMINATION PROCEDURE

1) LACK OF INFORMATION

a) There is no information regarding the effectiveness of hemodialysis or hemoperfusion for the removal of **pentetate** calcium trisodium from plasma.

F) Treatment should include recommendations listed in the ORAL EXPOSURE section when appropriate.

6.7 INHALATION EXPOSURE

6.7.1 DECONTAMINATION

A) DECONTAMINATION: Move patient from the toxic environment to fresh air. Monitor for respiratory distress. If cough or difficulty in breathing develops, evaluate for hypoxia, respiratory tract irritation, bronchitis, or pneumonitis.

B) OBSERVATION: Carefully observe patients with inhalation exposure for the development of any systemic signs or symptoms and administer symptomatic treatment as necessary.

C) INITIAL TREATMENT: Administer 100% humidified supplemental oxygen, perform endotracheal intubation and provide assisted ventilation as required. Administer inhaled beta adrenergic agonists if bronchospasm develops. Exposed skin and eyes should be flushed with copious amounts of water.

6.7.2 TREATMENT

A) SUPPORT

1) There is limited information on **pentetate** calcium trisodium overdose. In cases of trisodium overdose, treatment should be symptomatic and supportive.

B) MONITORING OF PATIENT

1) Monitor fluid and electrolyte status in patients with significant vomiting and/or diarrhea.

2) Monitor serum electrolytes and essential metals and obtain complete blood counts.

C) Treatment should include recommendations listed in the ORAL EXPOSURE section when appropriate.

6.11 ENHANCED ELIMINATION

A) LACK OF INFORMATION

1) There is no information regarding the effectiveness of hemodialysis or hemoperfusion for the removal of **pentetate** calcium trisodium from plasma.

7.0 RANGE OF TOXICITY

SUMMARY

THERAPEUTIC DOSE

MINIMUM LETHAL EXPOSURE

MAXIMUM TOLERATED EXPOSURE

WORKPLACE STANDARDS

7.1 SUMMARY

A) Pentetate calcium trisodium (Ca-DTPA) is usually well-tolerated. Deaths have been reported in three patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection. After receiving 14 grams of Ca-DTPA, one patient became comatose and died. The other two patients died after 14 days of daily treatment. Another patient with a less severe case of hemochromatosis did not experience any adverse effects after receiving 30 grams of Ca-DTPA by intravenous injection over 12 days.

7.2 THERAPEUTIC DOSE

7.2.1 ADULT

A) INTRAVENOUS

1) Treatment with **pentetate** calcium trisodium (Ca-DTPA) is most effective within the first 24 hours after internal contamination and should be started as soon as possible after suspected or known contamination. Chelation treatment should be started as soon as possible, even if treatment with Ca-DTPA cannot be started right away. Ca-DTPA is most effective when radiocontaminants are still circulating or are in interstitial fluids. Since radiocontaminants become sequestered in liver and bone, the efficacy decreases with time following internal contamination (Prod Info **Pentetate** Injection, 2004).

2) Ca-DTPA intravenous route (1 gram in 5 mL solution either by a slow intravenous push over 3 to 4

minutes or by intravenous infusion diluted in 100 to 250 milliliters of 5% dextrose in water, lactated Ringer's, or normal saline) is recommended. The intravenous route should be used of the route if internal contamination is not known or if multiple routes of internal contamination are likely (Prod Info Calcium Trisodium Injection, 2004)

3) Patients should drink plenty of fluids and void frequently to promote dilution of the chelated radiocontaminant in the urine and reduce radiation exposure directly to the bladder (Prod Info Calcium Trisodium Injection, 2004).

4) Other therapies may be needed (eg; Prussian blue, potassium iodide) if internal contamination with agents other than plutonium, americium, or curium is suspected, or if the radiocontaminant is unknown (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

5) INITIAL DOSE - A single intravenous dose of 1 gram of Ca-DTPA is recommended (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

6) MAINTENANCE DOSE - The day after the initial dose, if additional chelation therapy is needed, it is preferable to switch to **pentetate** zinc trisodium (Zn-DTPA), if available, due to safety concerns with prolonged Ca-DTPA administration. If Zn-DTPA is not available, treatment with Ca-DTPA may continue, but concomitant zinc supplementation should be given as needed. An intravenous dose of 1 gram of Ca-DTPA once daily is recommended for maintenance treatment (if Zn-DTPA is not available). Ca-DTPA should not be given simultaneously with Zn-DTPA (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

B) INHALATION

1) If internal contamination is only by inhalation within the preceding 24 hours, patients can receive Ca-DTPA by nebulized inhalation. Dilute Ca-DTPA for nebulization at a 1:1 ratio with sterile water or saline. After nebulization, patients should not swallow any expectorant (Prod Info Trisodium Injection, 2004).

7.2.2 PEDIATRIC

A) INTRAVENOUS

1) ADOLESCENTS -

a) INITIAL DOSE - An initial single intravenous dose of 1 gram of **pentetate** (Ca-DTPA) is recommended (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

b) MAINTENANCE DOSE - The day after the initial dose, if additional chelation therapy is needed, it is preferable to switch to **pentetate** zinc trisodium (Zn-DTPA), if available, due to safety concerns with prolonged Ca-DTPA administration. If Zn-DTPA is not available, treatment with Ca-DTPA may continue, but concomitant zinc supplementation should be given as needed. An intravenous dose of 1 gram of Ca-DTPA once daily is recommended for maintenance treatment (if Zn-DTPA is not available). Ca-DTPA should not be given simultaneously with Zn-DTPA (Prod Info Trisodium Injection, 2004).

2) CHILDREN LESS THAN 12 YEARS OF AGE -

a) INITIAL DOSE - An initial single intravenous dose of 14 milligrams per kilogram, not to exceed 1 gram, of **pentetate** calcium trisodium (Ca-DTPA) is recommended for children less than 12 years of age (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

b) MAINTENANCE DOSE - The day after the initial dose, if additional chelation therapy is needed, it is preferable to switch to **pentetate** zinc trisodium (Zn-DTPA), if available, due to safety concerns with prolonged Ca-DTPA administration. If Zn-DTPA is not available, treatment with Ca-DTPA may continue, but concomitant zinc supplementation should be given as needed. In pediatric patients (less than 12 years of age), an intravenous dose of 14 milligrams per kilogram (not to exceed 1 gram per day) of Ca-DTPA once daily is recommended for maintenance treatment (if Zn-DTPA is not available),(Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

B) INHALATION

1) ADOLESCENTS - If internal contamination is only by inhalation within the preceding 24 hours, patients can receive Ca-DTPA by nebulized inhalation. Dilute Ca-DTPA for nebulization at a 1:1 ratio with sterile water or saline. After nebulization, patients should not swallow any expectorant (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

2) CHILDREN LESS THAN 12 YEARS OF AGE - The safety and efficacy of the nebulized route of administration have not been established in children (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

7.3 MINIMUM LETHAL EXPOSURE

A) Deaths have been reported in three patients with severe hemochromatosis who received up to 4 times the recommended daily dose via intramuscular injection. After receiving 14 grams of Ca-DTPA, one patient became comatose and died. The other two patients died after 14 days of daily treatment (Prod Info Trisodium Injection, 2004).

7.4 MAXIMUM TOLERATED EXPOSURE

A) One patient with a less severe case of hemochromatosis did not experience any adverse effects after receiving 30 grams of Ca-DTPA by intravenous injection over 12 days (Anon, 2004).

7.6 WORKPLACE STANDARDS

A) ACGIH TLV Values for CAS12111-24-9 (American Conference of Governmental Industrial Hygienists, 2010):
1) Not Listed

B) NIOSH REL and IDLH Values for CAS12111-24-9 (National Institute for Occupational Safety and Health, 2007):
1) Not Listed

C) Carcinogenicity Ratings for CAS12111-24-9 :
1) ACGIH (American Conference of Governmental Industrial Hygienists, 2010): Not Listed
2) EPA (IRIS, 2004): Not Listed
3) IARC (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2006; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010a; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2008; IARC, 2004): Not Listed
4) NIOSH (National Institute for Occupational Safety and Health, 2007): Not Listed
5) MAK (DFG, 2002): Not Listed
6) NTP (NTP, 2005): Not Listed

D) OSHA PEL Values for CAS12111-24-9 (29 CFR 1910.1000, 2006):
1) Not Listed

8.0 KINETICS

ABSORPTION

DISTRIBUTION

METABOLISM

EXCRETION

8.1 ABSORPTION

A) THERAPEUTIC
1) INHALATION
a) Approximately 20% absorption from the lungs (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).
2) ORAL
a) Ca-DTPA is poorly absorbed in the gastrointestinal tract. In animal studies, absorption was approximately 5% (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

8.2 DISTRIBUTION

8.2.1 DISTRIBUTION SITES

A) TISSUE/FLUID SITES

1) Extracellular fluid, primarily - Ca-DTPA is rapidly distributed throughout the extracellular space. No significant penetration into erythrocytes or other cells. No accumulation in specific organs has been observed (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

8.3 METABOLISM

8.3.1 METABOLISM SITES AND KINETICS

A) WITH THERAPEUTIC USE

1) Metabolism of Ca-DTPA is minimal (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

8.4 EXCRETION

8.4.1 KIDNEY

A) Ca-DTPA is cleared from the plasma in the first few hours after dosing through urinary excretion by glomerular filtration. By 24 hours after administration, cumulative urinary excretion was more than 99% of the injected dose (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

8.4.4 OTHER

A) OTHER

1) BREAST MILK

a) It is unknown if Ca-DTPA is excreted in breast milk. However, radiocontaminants are known to be excreted in breast milk. Whether receiving chelation therapy or not, women with suspected or known internal contamination should not breast feed. Precautions should be taken when discarding breast milk (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

9.0 PHARMACOLOGY/TOXICOLOGY

9.1 PHARMACOLOGIC MECHANISM

A) Ca-DTPA is indicated for the treatment of known or suspected internal contamination with transuranium ions with molecular weight greater than uranium, specifically plutonium, americium, and/or curium, to increase rates of elimination (Prod Info **Pentetate** Calcium Trisodium Injection, 2004).

B) **Pentetate** calcium trisodium (Ca-DTPA) increases the rates of radiocontaminant elimination by forming stable chelates with metal ions. The calcium ion is exchanged for ions with higher binding capacity. The radioactive chelates are then excreted into the urine by glomerular filtration (Prod Info **Pentetate**
2004).

C) Ca-DTPA is most effective when radiocontaminants are still circulating or are in interstitial fluids. Since radiocontaminants become sequestered in liver and bone, the efficacy decreases with time following internal contamination. The day after initial dosing, if additional chelation therapy is needed, it is preferable to switch to **pentetate** zinc trisodium (Zn-DTPA), if available, due to safety concerns (eg; endogenous essential metal chelation) with prolonged Ca-DTPA administration. If Zn-DTPA is not available, treatment with Ca-DTPA may continue, but concomitant zinc supplementation should be given as needed (Prod Info
Trisodium Injection, 2004).

10.0 PHYSICOCHEMICAL

PHYSICAL CHARACTERISTICS

MOLECULAR WEIGHT

10.1 PHYSICAL CHARACTERISTICS

A) Ca-DTPA is a clear, colorless, hyperosmolar (1260 mOsmol/kg) solution (Prod Info
Trisodium Injection, 2004).

10.3 MOLECULAR WEIGHT

A) 497.4 Daltons (Prod Info **Pentetate** Calcium Trisodium Injection, 2004)

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