Ca-DTPA / Zn-DTPA
Pentetate Calcium Trisodium Injection
Pentetate Zinc Trisodium Injection

**PRODUCT INFORMATION**

**Ca-DTPA / Zn-DTPA**

**Exclusive “Dirty Bomb” Antidote**

*(For treatment of Plutonium, Americium, or Curiurn contaminants)*

- Approved by the United States Food and Drug Administration (FDA) as a pharmacological countermeasure to a potential radiological release/nuclear detonation
- Ca-DTPA/Zn-DTPA is indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination
- Increases the removal rate of radioactive materials from the body due to exposure from a Radiation Dispersal Device (RDD), commonly known as a “dirty bomb”
- After the initial dose of Ca-DTPA, it is recommended that therapy be continued with Zn-DTPA
- For use by federal/state/city/government agencies, public health agencies, hospitals and first responders
- Ca-DTPA/Zn-DTPA should be used with caution in individuals with severe hemochromatosis
- Nebulized chelation therapy may be associated with exacerbation of asthma

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**Pentetate Calcium Trisodium Injection**

Each mL contains:

- **Active**: 200 mg Pentetate Calcium Trisodium (from 158.17 mg pentetic acid, 40.24 mg calcium carbonate and NaOH).
- **Preservative**: None.
- **Inactives**: Water for Injection, Calcium Carbonate, Sodium Hydroxide for pH adjustment.
- **Sterile**, Non-pyrogenic

**Pentetate Zinc Trisodium Injection**

Each mL contains:

- **Active**: 200 mg Pentetate Zinc Trisodium (from 150.51 mg pentetic acid, 31.14 mg zinc oxide and NaOH).
- **Preservative**: None.
- **Inactives**: Water for Injection, Zinc Oxide, Sodium Hydroxide for pH adjustment.
- **Sterile**, Non-pyrogenic

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**Distributed by:** Akorn Inc.

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Each mL contains:
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Preservative: None.
Inactives: Water for Injection, Calcium Carbonate, Sodium Hydroxide for pH adjustment.
Sterile, Non-pyrogenic

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Each mL contains:
Active: 200 mg Pentetate Zinc Trisodium (from 150.51 mg pentetic acid, 31.14 mg zinc oxide and NaOH).
Preservative: None.
Inactives: Water for Injection, Zinc Oxide, Sodium Hydroxide for pH adjustment.
Sterile, Non-pyrogenic

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wholesaler order entry numbers

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Pentetate Calcium Trisodium Injection

**DESCRIPTION**

Pentetate Calcium Trisodium Injection contains the non-radioactive calcium chelate form of DTPA (diethylenetriamine pentaacetic acid). Pentetate Calcium Trisodium Injection is available in the following concentrations:

- 1000 mg pentetate calcium trisodium per mL
- 200 mg pentetate calcium trisodium per mL

**INDICATIONS AND USES**

Pentetate Calcium Trisodium Injection is indicated for the treatment of individuals who have been accidentally or suspected internal contamination with transuranium elements has occurred. There is little or no binding of the chelating agent to non-radioactive elements. Pentetate Calcium Trisodium Injection is the preferred treatment for such individuals. Pentetate Calcium Trisodium Injection is administered through slow intravenous injection over a period of minutes. Pentetate Calcium Trisodium Injection contains the equivalent of 1000 mg of pentetate calcium trisodium per mL.

**CONTRAINDICATIONS**

- Pregnant or lactating women
- Patients with a known hypersensitivity to Ca-DTPA

**WARNINGS**

- Use of pentetate calcium trisodium intravenously and orally may cause severe allergic reactions.
- Oral chelation therapy may be associated with exacerbation of asthma.

**SIDE EFFECTS**

The most frequent side effect is the development of a transient hypocalcemia. Pentetate Calcium Trisodium Injection is supplied as a clear, colorless, hyperosmolar (1260 mOsmol/kg) sterile, non-pyrogenic and suitable for intravenous administration. Each mL of solution contains the equivalent of 1000 mg of pentetate calcium trisodium. Pentetate Calcium Trisodium Injection is supplied in sterile, type I glass, opaque, plastic ampoules containing 1 mL and 2 mL of solution.

**DOSAGE AND ADMINISTRATION**

1.0 gram of solution is administered once a day intravenously. A single intravenous dose of 1.0 gram of Ca-DTPA may be administered over up to 2 hours. If Ca-DTPA is administered orally, it should be given in divided doses and the total oral dose should not exceed 1.0 gram per day. Pentetate Calcium Trisodium Injection is supplied in sterile, type I glass, opaque, plastic ampoules containing 1 mL and 2 mL of solution.
Plasma retention and urinary excretion data were obtained in 2 subjects that received Cae-DTPA. Chelation treatment should be given as soon as possible after known or suspected internal contamination with radiocontaminants. The individual who received the greatest exposure survived and was treated with Cae-DTPA. The other 4 individuals died after receiving a total of 14 gram Cae-DTPA, and the other two died after receiving a total of 12 gram of Zn-DTPA. These observations indicate that the inhaled product was absorbed and resulted in a comparable amount of internal contamination with radiocontaminants.

In animal studies, high doses of Cae-DTPA led to multiple radiocontaminants, or when the radiocontaminants are unknown, additional radiographic images or radionuclide counting data should be obtained. Additional radiographic images or radionuclide counting data should also be obtained to determine the severity of internal contamination.

In a study of rodents internally contaminated with plutonium, the rate of plutonium absorption was determined. To identify the rate of absorption, the animals were monitored for the presence of internal contamination. The results indicated that the rate of absorption was slower in rodents contaminated with plutonium than in rodents contaminated with other radiocontaminants.

Ca-DTPA is supplied as a clear, colorless, hyperosmolar (1260 mOsmol/kg) solution and is isotonic. Ca-DTPA is supplied as a colorless, hyperosmolar (1260 mOsmol/kg) solution and is isotonic. Ca-DTPA is supplied as a colorless, hyperosmolar (1260 mOsmol/kg) solution and is isotonic.

Intravenous administration of Ca-DTPA is recommended and should be performed initial dose is 1 gram. The dose is based on body size adjustment for an intravenous drug that is administered by the intravenous route. (See Dosage and Administration).

The safety and effectiveness of the intramuscular route of injection have not been established in the pediatric population. Reactions to treatment were noted, including vomiting, diarrhea, and abdominal pain.

To establish an elimination curve, a quantitative baseline estimate of the total dose of radiocontaminants is made by incorporating the radiocontaminants into the serial analysis of the urine. If appropriate, vitamin or mineral supplements should be given in the treatment of individuals who were contaminated with radiocontaminants.

To develop long-term response data and information on the risk of development of internal contamination, the results of serial analysis of the urine were incorporated into the serial analysis of the urine.

The duration of chelation treatment depends on the amount of internal contamination. Patients should be monitored for evidence of the presence of radiocontaminants and for the presence of other signs and symptoms of internal contamination.

The safety and effectiveness of Zn-DTPA was established in the adult population. Plasma retention and urinary excretion data were obtained in 2 subjects that received Zn-DTPA. Chelation treatment should be given as soon as possible after known or suspected internal contamination with radiocontaminants.

In another study, rodents contaminated with aerosolized plutonium and multiple radiocontaminants, or when the radiocontaminants are unknown, additional radiographic images or radionuclide counting data should be obtained. Additional radiographic images or radionuclide counting data should also be obtained to determine the severity of internal contamination.

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