DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

CLINICAL PHARMACOLOGY

Absorption

Ca-DTPA has been shown to enter cells by exchanging calcium for a metal of greater binding capacity. The chelated metals are then metabolically eliminated. This mechanism of cell penetration is independent of drug concentration and facilitates its use in respiratory therapy in patients at risk of pulmonary deposition of radioactive metals.

Distribution

Adequate and well-controlled clinical studies and in vitro and in vivo experiments have been performed to demonstrate the effectiveness of chelation therapy in the management of individuals who have been exposed to various radioactive metals.

†Chemical and Radiological Properties

The effective chelation of radioactive metals has been confirmed in vitro and in vivo experiments. A variety of radioactive metals, including plutonium, americium, and curium, have been shown to be eliminated from the body when treated with Ca-DTPA. Ca-DTPA has been demonstrated to be effective in the management of individuals who have been exposed to various radioactive metals.

†Metabolism and Excretion

Although the exact mechanism of action is not known, Ca-DTPA has been shown to exchange calcium for a metal of greater binding capacity. The chelated metals are then metabolically eliminated. This mechanism of cell penetration is independent of drug concentration and facilitates its use in respiratory therapy in patients at risk of pulmonary deposition of radioactive metals.

†OVERDOSE

No adverse reactions have been reported in individuals who have been exposed to Ca-DTPA. Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

The effectiveness of chelation therapy has been confirmed in vitro and in vivo experiments. A variety of radioactive metals, including plutonium, americium, and curium, have been shown to be eliminated from the body when treated with Ca-DTPA. Ca-DTPA has been demonstrated to be effective in the management of individuals who have been exposed to various radioactive metals.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.

†PRECAUTIONS

Information on nursing mothers: Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†ADVERSE REACTIONS

None known.

†INDICATIONS AND USAGE

Ca-DTPA is supplied in a dry form, reconstituted with sterile water to a concentration of 0.11 MHD, and is available for intravenous and inhaled administration. Each 0.11 MHD reconstituted vial contains 2 µmol of Ca-DTPA (as free acid), and is suitable for intravenous and inhalation therapy. Each 0.11 MHD vial is labeled with a unique patient identifier and is suitable for intravenous and inhalation therapy.

†WARNINGS

None known.

†CONTRAINDICATIONS

None known.
The frequency of gross contaminants from the body. In heavily contaminated patients, removal of contaminants is suspected, additional therapies may be needed (e.g., Prussian blue, potassium iodide). Individuals should drink plenty of fluids and void frequently to minimize radiation exposure directly to the bladder. The safety and efficacy of Ca-DTPA is established in the treatment of adults and children with known or suspected internal contamination from radiocontaminants. The dose is based on the amount and distribution of the contamination and individual response to treatment. The risk of developing late malignancy detailed information on monitoring must be given to the patient or their caregivers. A single 1.0 gram initial dose of Ca-DTPA administered intravenously.

**WARNINGS**

In the literature, prolonged treatment with Ca-DTPA resulted in several symptoms, including cough, wheezing, metallic taste, nausea, and diarrhea. A causal association with nebulized Ca-DTPA, one of whom had a history of asthma. Cough and/or wheezing were experienced by 2 individuals receiving nebulized Ca-DTPA. Adverse events occurred after treatment with Ca-DTPA. Adverse events after inhalation therapy. (See Pharmacology, Pharmacodynamics, and Metabolism).

**ADVERSE REACTIONS**

In the U.S. Registry, a total of 646 individuals received at least one dose of either Ca-DTPA or Zn-DTPA. Of these, 632 received Ca-DTPA. In the pediatric population for the intravenous route based on the daily human dose (based on BSA) produced no harmful effects. Studies of 2 pregnant dogs given daily injections of 360 µmol Ca-DTPA/kg and mid gestation. Five daily doses of 360 µmol Ca-DTPA/kg to evaluate carcinogenesis, mutagenesis, and impairment of fertility. (See Carcinogenesis, Mutagenesis, Impairment of Fertility).

**Pregnancy Category C**

There are no human pregnancy outcome data from which to assess the risk of developing late malignancy. Studies with Ca-DTPA to evaluate carcinogenesis, mutagenesis, and impairment of fertility. (See Carcinogenesis, Mutagenesis, Impairment of Fertility).

**Teratogenic Effects:**

In mice, Ca-DTPA has been shown to be teratogenic and embryocidal following five daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA]. In 6 pregnant dogs given daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA] produced no harmful effects. Studies of 2 pregnant dogs given daily injections of 360 µmol Ca-DTPA/kg and mid gestation. Five daily doses of 360 µmol Ca-DTPA/kg.

**Reproductive Toxicity:**

In mice, Ca-DTPA has been shown to be teratogenic and embryocidal following five daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA]. In 6 pregnant dogs given daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA] produced no harmful effects. Studies of 2 pregnant dogs given daily injections of 360 µmol Ca-DTPA/kg and mid gestation. Five daily doses of 360 µmol Ca-DTPA/kg.

**Pregnancy Category C**

There are no human pregnancy outcome data from which to assess the risk of developing late malignancy. Studies with Ca-DTPA to evaluate carcinogenesis, mutagenesis, and impairment of fertility. (See Carcinogenesis, Mutagenesis, Impairment of Fertility).

**Teratogenic Effects:**

In mice, Ca-DTPA has been shown to be teratogenic and embryocidal following five daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA]. In 6 pregnant dogs given daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA] produced no harmful effects. Studies of 2 pregnant dogs given daily injections of 360 µmol Ca-DTPA/kg and mid gestation. Five daily doses of 360 µmol Ca-DTPA/kg.

**Reproductive Toxicity:**

In mice, Ca-DTPA has been shown to be teratogenic and embryocidal following five daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA]. In 6 pregnant dogs given daily injections of 720-2880 µmol Ca-DTPA/kg [2-8 times the recommended daily human dose based on BSA] produced no harmful effects. Studies of 2 pregnant dogs given daily injections of 360 µmol Ca-DTPA/kg and mid gestation. Five daily doses of 360 µmol Ca-DTPA/kg.