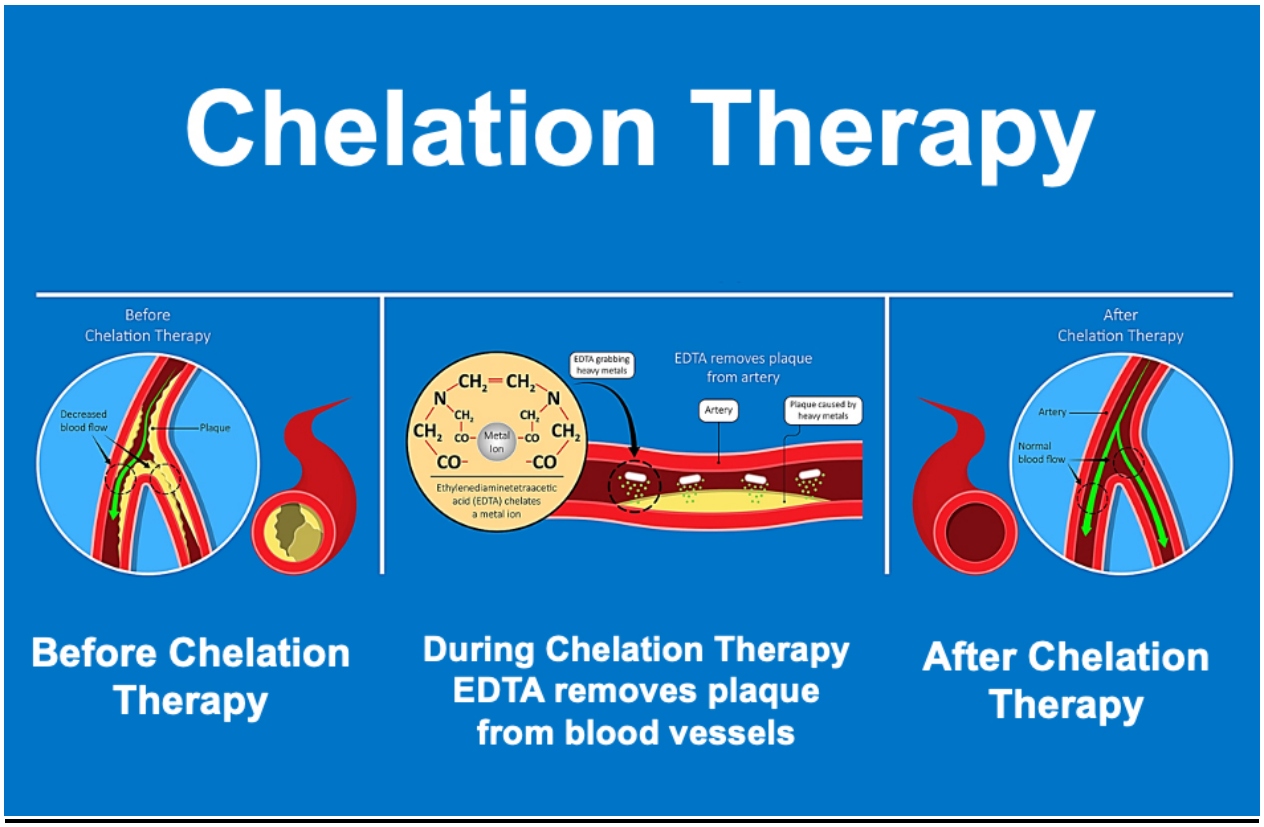
Chelation Therapy

Edetate disodium, a chelating agent with affinity for divalent and trivalent metals, is indicated in the treatment of hypercalcemia. Because the drug can decrease blood calcium levels too rapidly (causing tetany, cardiac arrhythmias, and respiratory arrest), it now is only rarely used. Due to its pharmacodynamic actions that oppose those of the cardiac glycosides, edetate disodium was once used to treat arrhythmias associated with digitalis toxicity, but digoxin immune Fab is now the preferred agent for this condition. Edetate disodium should not be confused with its calcium salt (calcium EDTA), which is used to treat lead toxicity. In the 1950s and 1960s, edetate disodium was used for atherosclerotic vascular disease despite a lack of clinical data to support its efficacy. Only 1 large, placebo-controlled, randomized, double-blind study has been conducted to evaluate this use of edetate disodium and this study showed no significant symptomatic or angiographic improvement in the EDTA group relative to placebo. Nevertheless, there continues to be sustained interest in using this drug for the treatment of atherosclerosis. Based on a recent clinical trial (PATCH), there is no evidence to support a benefit (evaluated exercise time to ischemia, exercise capacity, and quality of life measurements) of chelation therapy (Endrate®) in patients with ischemic heart disease including stable angina. Because of the possibility of potentially lethal adverse effects, edetate disodium should not be used for the treatment of generalized arteriosclerosis due to advancing age. Edetate disodium was approved by the FDA for clinical use in 1956.



Mechanism of Action

Edetate disodium preferentially binds calcium ions, forming a stable, soluble complex that is then excreted by the kidneys. Serum calcium levels decrease quickly following intravenous administration of edetate disodium, and 1gm of edetate disodium has the potential to combine with 120 mg of calcium. The decrease in calcium precipitated by administration of the drug antagonizes the inotropic and chronotropic effects that digitalis glycosides exert on the ventricles of the heart, thereby helping to control digitalis-induced ventricular arrhythmias. In addition, edetate disodium exhibits negative cardiac inotropic activity. A too rapid decrease in serum calcium induced by edetate disodium can precipitate hypocalcemic tetany, seizures, severe cardiac arrhythmias, and respiratory arrest, but these effects are usually related to high doses or rapid infusion rates. Slow IV infusion allows time for calcium in bone to be mobilized to replenish the serum calcium pool, thereby lowering the risk of developing these adverse effects. The concentration of calcium ions in the cerebrospinal fluid is not affected by edetate disodium administration.

Edetate disodium also chelates and enhances the excretion of other trace metals including magnesium and zinc, and although the drug does not chelate potassium, the administration of edetate disodium can increase renal excretion and decrease serum concentration of this mineral, possibly producing hypokalemia. At one time, it was thought the calcium-lowering actions of edetate disodium could be utilized in the management of atherosclerosis but this use has been refuted. Edetate disodium is still advocated as a treatment for this condition and now its proponents claim that the drug

works by chelating iron and copper, thereby impairing the generation of free radicals. This mechanism has not been verified. The use and mechanism of action of edetate disodium for this condition remains speculative.

Pharmacokinetics

Edetate disodium is administered intravenously, and although the distribution of the drug has not been established, it does not appear to cross the blood-brain barrier to a significant extent. No metabolism of the drug occurs, and an intravenous dose is excreted primarily as the calcium chelate. Approximately 95% of a dose is excreted in the urine within 24 hours.

Indications

For the treatment of hypercalcemia, or, for treatment of cardiac glycoside-induced arrhythmias (i.e., ventricular arrhythmias associated with digitalis toxicity):

Intravenous dosage:
Adults: 50 mg/kg/day (up to 3 g/day) administered by slow IV infusion. Frequency and duration of administration are quite variable, and should be determined based on the patient's serum calcium. Five consecutive daily doses may be administered, followed by 2 days without medication, repeating these courses as necessary to a total of 15 doses.

Maximum Dosage Limits:
Adults: 50 mg/kg/day IV, not to exceed 3 g/day.
Elderly: 50 mg/kg/day IV, not to exceed 3 g/day.
Adolescents*:* Safety and efficacy have not been established, although doses up to 70 mg/kg/day IV (not to exceed 3 g/day IV) have been used.
Children: Safety and efficacy have not been established, although doses up to 70 mg/kg/day IV have been used.

Patients with Hepatic Impairment Dosing:
Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.

Patients with Renal Impairment Dosing:
Specific guidelines for dosage adjustments in renal impairment are not available; edetate disodium is contraindicated in anuric patients. Patients with renal impairment may be at higher risk for adverse effects.

General Administration Information

For storage information, see the specific product information within the How Supplied section.

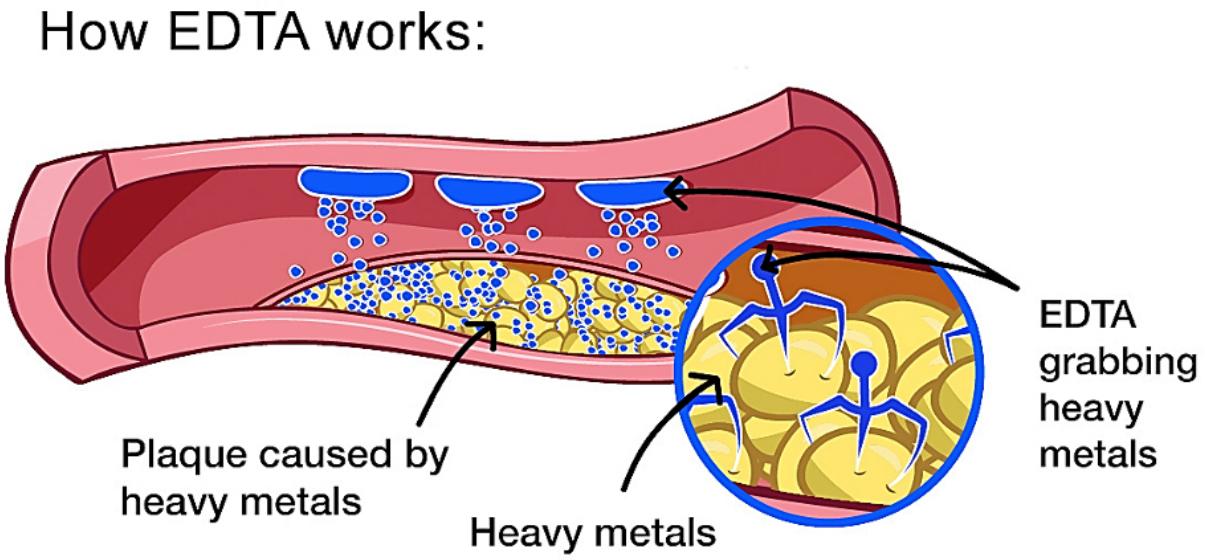
NOTE: Because of the possibility of potentially lethal adverse effects, edetate disodium should not be used for the treatment of generalized arteriosclerosis due to advancing

age. There is no acceptable scientific evidence to support the use of edetate disodium in treating atherosclerotic, coronary, or peripheral vascular disease.

Route-Specific Administration

Injectable Administration
Visually inspect parenteral products for particulate matter and discoloration prior to administration whenever solution and container permit.

Intravenous infusion
Do not administer rapidly; rapid administration or high serum concentrations of edetate disodium may cause a sudden drop in serum calcium concentrations which may produce hypocalcemic tetany, convulsions, severe cardiac arrhythmias, and death from respiratory arrest. Infuse diluted solution slowly IV over 3 hours or more, preferably over 4—6 hours. Care should be taken to avoid extravasation because the drug is very irritating to extravascular tissue. Following infusion, the patient should remain in bed for a few minutes to avoid postural hypotension.
Dilution
Adults: Dilute calculated dose in 500 mL of 5% Dextrose or sodium chloride injection. *Children*: Dilute calculated dose in a sufficient amount of 5% Dextrose or sodium chloride injection to make an infusion solution of concentration no greater than 3%.
Intravenous Administration
Edetate disodium (EDTA) is administered by IV infusion.



Summary Chelation Therapy

Chelation therapy detoxifies the body and cleanses the blood by eliminating harmful metals accumulated in healthy tissues. Our Heavy Metal IV therapy is aimed at protecting the body against the damage caused by heavy metals and restoring internal health. Chelation therapy is a method of removing heavy metals that build up in the body's healthy cells and tissues. As it involves the intravenous administration of medications, it is commonly referred to as IV chelation therapy. During our Heavy Metal IV therapy, a chemical compound is injected into the blood. This compound is known as EDTA (ethylene diamine tetra-acetic acid), a synthetic amino acid with the ability to bind to and remove metals and minerals like lead, iron, calcium and copper from the blood. This enters the bloodstream and binds to molecules of metals and minerals so that they can be easily removed from the body. The elimination of these toxic metals from the body enhances general health and fortifies the body's ability to defend itself against illness. On a daily basis, we are exposed to a variety of heavy metals including mercury, iron, arsenic and lead. The most common sources of exposure to heavy metals are:

- Polluted water
- Ingestion of lead-containing paint
- Air containing high levels of pollutants

A build-up of metals may also occur due to genetic factors or certain treatments recommended for the management of illnesses. For example, a genetic issue may cause an accumulation of copper in the body resulting in the symptoms of copper poisoning. Similarly, the absorption of excessively high levels of iron in the intestine from food or overuse of iron supplements may lead to iron overload.Those who require blood transfusions are also at risk of iron overload, and others who undergo dialysis may be at risk of a build-up of aluminum in the blood. These metals cannot be eliminated completely via the body's excretory organs. As a result, they can accumulate in healthy tissues. As this build-up of metals increases, it may affect the body's normal physiological functions. It can also affect general health and lead to fatigue as well as changes in the skin and other tissues. Therefore, it is important to eliminate these toxic chemicals from the body in order to restore energy levels and slow down other degenerative processes. Chelation therapy with our Heavy Metal IV reduces the overload of toxic metals in the blood and healthy tissues. It offers a safe and effective way to eliminate metals from the blood, including:

- Iron
- Lead
- Mercury
- Arsenic
- Nickel
- Copper

Chelation therapy supports the body's natural detoxification processes. Our Heavy Metal IV can be beneficial for those with a build-up of heavy metals due to reasons such as:

- Chronic exposure to lead in paint or other industrial materials
- Certain disorders that can cause an accumulation of copper or other metals in the body
- Long-term use of iron supplements

- Residing in polluted cities

The Heavy Metal IV facilitates the faster removal of toxins, restoring optimal health by detoxifying the body. It offers several benefits such as:

- Supporting the function of the skin and other organs
- Protecting healthy tissues against damage
- Slowing down age-related changes
- Reducing fatigue
- Improving energy levels

At Vitamin Injections London, our Heavy Metal detox is a fast and safe method of flushing out toxic metals from the body, leaving it healthier and more energised.