

## **FDA Public Health Advisory**

### **Edetate Disodium (marketed as Endrate and generic products)**

*This information reflects FDA's current analysis of data available concerning this drug. FDA intends to update this when additional information or analyses become available.*

FDA is issuing this public health advisory to alert patients and healthcare professionals about important safety information concerning the drug Edetate Disodium. There have been cases where children and adults have died when they were mistakenly given Edetate Disodium instead of Edetate Calcium Disodium (Calcium Disodium Versenate) or when Edetate Disodium was used for "chelation therapies" and other uses that are not approved by the FDA. As a result, FDA is reviewing the benefit/risk profile of Edetate Disodium to determine if the benefits for its intended use continue to outweigh the serious risks.

These two drugs have very similar names and are commonly referred to only as "EDTA." As a result, the two products are easily mistaken for each other when prescribing, dispensing, and administering them. Edetate Disodium and Edetate Calcium Disodium work by binding with heavy metals or minerals in the body allowing them to be passed out of the body through the urine.

The FDA originally approved the two drugs for very specific and very different purposes as described below.

- Edetate Disodium was approved many years ago as an emergency treatment for certain patients with a condition called hypercalcemia (very high levels of calcium in the blood) or certain patients with heart rhythm problems as a result of very high amounts of digitalis in the blood. However, there are newer drugs that have been approved since that time that treat these conditions.
- Edetate Calcium Disodium was also approved many years ago and is still used to reduce dangerously high blood lead levels (severe lead poisoning). This drug is medically necessary because there are very few other drugs available to treat severe lead poisoning.

Over time, a number of uses that are not FDA approved for these products have evolved in clinical settings. Among these uses are the removal of other heavy metals from the blood and the treatment of heart disease (coronary artery disease), commonly referred to "chelation therapies."

On March 3, 2006, the Centers for Disease Control and Prevention published an article in the *Morbidity and Mortality Weekly Report* documenting the deaths of people given Edetate Disodium instead of Edetate Calcium Disodium (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5508a3.htm>). FDA was informed early in 2007 of an additional child's death as a result of a mix-up between the two drugs. Because of the potential for these medication errors to be fatal, the CDC recommended that hospitals evaluate their need to keep Edetate Disodium stocked in their pharmacies. FDA supports this recommendation as a means of reducing the risk of confusing the two drugs.

FDA is issuing this advisory to highlight the following important safety considerations until the ongoing evaluation of the risks and benefits of Edetate Disodium is complete.

- Because of the potential for these medication errors to be fatal, the FDA and CDC recommend that hospitals evaluate their need to keep Edetate Disodium stocked in their pharmacies.
- If your facility determines that there is no need to have a supply of Edetate Disodium, consider removing the product from stock to reduce the risk of confusion with Edetate Calcium Disodium.
- The safety or effectiveness of Edetate Disodium or Edetate Calcium Disodium for use in removing heavy metals and toxins from the body, use in treating coronary artery disease, or other uses not described in the labeling for the product have not been established.
- Children and adults who are to be treated for lead poisoning should **only** be given the Edetate Calcium Disodium (Calcium Disodium Versenate) form of "EDTA."
- Use the full product name. Do not use the abbreviation "EDTA" when prescribing or dispensing an order for either of the drugs.
- Consider including the indication for use of the product on the prescribing order.
- Hospitals, pharmacies and healthcare providers should always check the prescribing order and the label of the drug to confirm that the correct drug has been selected for use before dispensing and administering the drug to a patient.

FDA will determine further regulatory actions once we complete our evaluation of the safety and efficacy of Edetate Disodium.